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ABSTRACT

The proceedings of the First International Congress on Clinical Pharmacy Education, which introduced pharmacy educators from outside of North America to the U.S. clinical pharmacy component of education and practice are presented in more than 20 separate papers. The program's objectives were: (1) to provide a historical overview of the development of clinical pharmacy and examine its predicted future and environment; (2) to offer an orientation to clinical pharmacy practice and education through on-site visitations; (3) to provide a look at how clinical pharmacy is viewed by the physician, nurse, pharmacist, student, and observer; (4) to provide the basic considerations for the development of the clinical component of pharmacy education; and (5) to offer a discussion of how to develop clinical pharmacy education in a pharmacy school. Sections include: clinical pharmacy; how others view clinical pharmacy (physician, nurse, pharmacist, student, and observer perspectives); basics of the clinical component of pharmacy education (patient interview and monitoring, patient education, drug information, and integration of instruction); and clinical pharmacy education: how to do it (administration, basic and clinical sciences, supporting services, program evaluation, and instructional methodology). Foreign participants came from the following countries: Saudi Arabia, Korea, Philippines, Egypt, Ghana, Rhodesia, Japan, New Zealand, Nigeria, Belgium, England, South Africa, W. Germany, Peru, Australia, India, Netherlands, Wales, and Iran. (LC)

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# PROCEEDINGS
# of the
# FIRST INTERNATIONAL CONGRESS
# on
# CLINICAL PHARMACY EDUCATION

JULY 13-16, 1976
MINNEAPOLIS, MINNESOTA

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# PROCEEDINGS
# of the
# FIRST INTERNATIONAL CONGRESS
# on
# CLINICAL PHARMACY EDUCATION

Co-sponsored by

College of Pharmacy, University of Minnesota
American Association of Colleges of Pharmacy

Program Chairman & Editor
Lawrence C. Weaver, Ph.D.

# PURPOSE OF THE CONGRESS

The purpose of this International Congress was to introduce pharmacy educators from outside of North America to the clinical pharmacy component of education and practice. In addition, the program should be useful to those pharmacy educators in North America who are interested in expanding and strengthening their present clinical pharmacy programs.

Objectives: The program attempted to provide

- an historical overview of the development of clinical pharmacy and a look at its predicted future and environment;
- an orientation to clinical pharmacy practice and education through on-site visitations;
- a look at how clinical pharmacy is viewed by the physician, nurse, pharmacist, student, and observer;
- the basic considerations for the development of the clinical component of pharmacy education;
- a discussion of how to go about developing clinical pharmacy education in a pharmacy school.

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# OPENING OF THE CONGRESS

Presiding:

Allen I. White, Ph.D.
Dean, College of Pharmacy
Washington State University
Past President, AACP

# GREETINGS OF THE AACP TO THE INTERNATIONAL CONGRESS ON CLINICAL PHARMACY EDUCATION

Tom S. Miya, Ph.D., Professor, School of Pharmacy and Pharmacal Sciences, Purdue University, President, AACP

It is a pleasure for me to bring the greetings of the Association and its Board of Directors to this Congress. The AACP is happy to co-sponsor this first International Congress on Clinical Pharmacy Education. I particularly wish to extend a warm hand of welcome to our oversea's visitors and hope to have the opportunity to greet each and everyone of you personally.

Congratulations are in order to Dean Lawrence Weaver and the University of Minnesota for making such a congress possible. Someone once said, "The world is moving so fast these days that the man who says it can't be done is generally interrupted by someone doing it". With the general impetus on the clinical component in pharmacy education I am surprised that a congress of this nature has not been held before, but I am certainly not surprised that Dean Weaver would be the individual to spearhead and bring such a congress to fruition.

The primary purpose of this Congress is to introduce pharmacy educators from outside North America to the clinical component of pharmacy education and practice. For those pharmacy educators within North America this Congress will accent the Report of the Study Commission on Pharmacy and the Report of the AACP-sponsored Pharm.D. conference held in Kansas City last fall.

The opinion of the Study Commission is that the pharmacists of the future will provide drug services of even greater benefit to patients and to society. Some of these services are being discussed within the framework of this Congress. Let us not forget that education and educators have the responsibility not to maintain the status quo, but to meet the needs of the 'march of time'.

Albert Einstein said, "To raise new questions, new possibilities, to regard old problems from a new angle, requires creative imagination". I hope that this Congress will spur all of you to that type of creative imagination which will make the profession of pharmacy grow in stature and in service.

# GREETINGS FROM THE UNIVERSITY OF MINNESOTA

Lyle A. French, M.D., Vice President, Health Science Center, University of Minnesota.

I am very delighted to welcome you all here to the University of Minnesota and to this International Congress on Clinical Pharmacy Education. We are delighted to be co-sponsors of such a program. The reason you are here at such a program is highly important to us because this type of education and career model is a top priority for this Health Sciences Center.

The day is long past in which health professionals can function in isolation. The need and demand is for a coordinated, cooperative, integrated health delivery system; and, frankly, this will never come about until we get an integrated educational system. No longer can practicing pharmacists sit alone in a corner store and simply dispense pills or, in fact, the educators sit in Appleby Hall. They must become a more active component of the health care team and this can be accomplished, I believe, through clinical pharmacy programs. I appreciate the resistance to this by many practicing pharmacists and, of course, by many physicians but the fact is -- we must put behind us our older, fixed concepts. We must expand our horizons and clinical pharmacy is just such an expansion that is highly needed.

I wish you good luck in the next three days. I know it will be profitable for you and all of your educational systems.

# ORIENTATION TO CONGRESS

Lawrence C. Weaver, Ph.D., Dean, College of Pharmacy, University of Minnesota.

The way to get ahead is to start now. If you start now, you will know a lot next year that you don't know now and that you would not have known next year if you had waited. - - - William Feather.

The patient-oriented practice of pharmacy is emerging as the most exciting development in the profession in the past several decades. It has had a profound effect on pharmacy education. The purpose of this International Congress is to introduce pharmacy educators from outside of North America to the clinical pharmacy component of education and practice as it exists. In addition, the program will be useful to those pharmacy educators in North America who are interested in expanding and strengthening their present clinical pharmacy programs.

Objectives: The program will provide

1. An historical overview of the development of clinical pharmacy and a look at its predicted future and environment;

2. An orientation to clinical pharmacy practice and education through on-site visitations;

3. A look at how clinical pharmacy is viewed by the physician, nurse, pharmacist, student and observer;

4. The basic consideration for the development of the clinical component of pharmacy education;

5. A discussion of how to go about developing clinical pharmacy education in a pharmacy school.

Many pharmacy schools are willing to show you their programs if you choose to visit their campus during your stay in North America. You are encouraged to make contact with representatives of those schools of interest to you during the next week.

As a result of these meetings we hope there will be cooperative arrangements developed between schools within and outside North America. This would benefit greatly those schools outside North America in designing a clinical component to their pharmacy curriculum. I would suggest that speakers on this program represent a rich resource to start your contacts.

On Friday morning, July 16, participants in the Congress will be guest of the sponsors of the AACP-AFPE Teachers Seminar on Pharmacology and Clinical Pharmacy. You are encouraged to attend this seminar, which will be concerned with an in-depth consideration of teaching clinical pharmacy.

This program is being co-sponsored by the University of Minnesota College of Pharmacy and the American Association of Colleges of Pharmacy. In addition, every school listed in the program is a sponsor, since they are assisting in the financing of the Congress by supporting the program speakers from their own schools.

The program will involve presentations by guest speakers, with an opportunity for the participants to direct questions to a panel of the speakers after each segment of presentations. We encourage you to present your questions at the time of the panel discussions. I am looking forward to the next three days of productive sharing of experiences with the clinical pharmacy component of education.

# CLINICAL PHARMACY: YESTERDAY, TODAY AND TOMORROW

Presiding:

Allen I. White, Ph.D.
Dean, College of Pharmacy
Washington State University
Past President, AACP

# THE DEVELOPMENT OF CLINICAL PHARMACY

Donald C. Brodie, Ph.D., Adjunct Professor of Pharmacy and Medicine and Roger A. Benson, Ph.D., Research Associate, Schools of Pharmacy and Medicine, University of Southern California.

## INTRODUCTION

The association of the adjective "clinical" as a modifier of the noun "pharmacy" is of recent origin, although the notion of a clinical pharmacy service has several historical precedents. There were occasional appearances of the term in the literature of the recent past, but a critical review of the literature forces one to conclude that the word clinical, when used in today's context, first appeared in the middle 1960's. Writing in the report of the Commission on Pharmaceutical Services to Ambulant Patients by Hospitals and Related Facilities, in 1965, Brodie stated that "The ultimate goal of the services of pharmacy must be the safe use of drugs by the public. In this context, the mainstream function of pharmacy is clinical in nature, one that may be identified accurately as drug-use control."[1] Drug-use control was then defined as "the sum total of knowledge, understanding, judgements, procedures, skills, controls, and ethics that assures optimal safety in the distribution and use of medication."

Viewing the report of the Commission retrospectively, one can see that the concept of clinical pharmacy was evolving, that the nature of the pharmacist's services was being re-defined, and that clinical practice would apply equally to providing the drug-related needs of inpatients in hospitals and ambulant patients served by community pharmacists. "In the future," the report continued, "pharmacists would have increasing opportunities to participate in the distribution of drugs in a clinical situation. Emerging patterns...in hospitals place the pharmacist on the floor, interpreting chart orders for medication, preparing the medication for the nursing staff, and providing consultative drug information when required."

In 1966, Parker, speaking to the American Society of Hospital Pharmacists, defined clinical pharmacy as "a concept or a philosophy emphasizing the safe and appropriate use of drugs in patients."[2] The Study Commission on Pharmacy in 1975 reported that instruction in clinical pharmacy by the colleges of pharmacy "emphasizes services to patients," and that the "one common idea (in the clinical pharmacy concept) is an emphasis upon drugs as they are utilized by and in the patient. It is the joining of drug and patient which is inseparable...".[3]

Today, the word "clinical" is used extensively in both the educational and practice literature of pharmacy to describe, for the most part, a mode of practice and a role for the pharmacist. Fortunately, the profession has had the wisdom to allow the passage of time to give clarity to the term, should it remain in use. The term has been used to describe an attitude, a concept, an emphasis, an orientation, a mode of practice, a role, a philosophy, and a "type" of pharmacist. Some believe clinical pharmacy to be a new creation - a new form of pharmacy practice. Many people, on the other hand, believe that the term is redundant - that it has no justified use because pharmacy practice by its very nature is a personal health service and, thereby, is clinical. Some believe that the term clinical, when used to describe a pharmacist, is not only redundant, but is also divisive. They point to the conflicts that exist within the profession because we have classified pharmacists on the basis of where they practice and the addition of still a third category can only worsen the situation. Some believe that use of the term clinical will assist in changing the image of the pharmacist from that of the traditional "corner druggist" to a modern practitioner, a modern drug expert. This presupposes that the pharmacist's competencies and performance will change and thereby justify a change in his public image. This is, indeed, a worthy goal for pharmacy, and one that is consistent with the goals of the other health professions who are also attempting to free their practitioners from the stigma of long-standing stereotyped images.

Physicians and pharmacists have feuded over professional image and territorial prerogatives for generations, and it is not surprising that differences of opinion exist between the two professions regarding the meaning and use of the word clinical. In the past, the boundaries between medicine and pharmacy were poorly defined. For example, Wilson, in his treatise Drugs and Pharmacy in the Life of Georgia 1733-1959, says that "for one hundred and fifty years following the establishment of the Colony (Georgia), pharmacy and medicine were not distinguished one from the other by law or by practice, since in most instances, the individual served in the dual capacity without formal educational requirements or professional background of training and experience other than that offered by the preceptorship system."[4]

The conflict over the use of the term clinical is just another milestone in the historical relationships between the two professions. It comes at a time when new roles are emerging, traditional roles are broadening and the universe of both professional and technical health workers is expanding and exists today in a state of confusion. The basic issue which seems to transcend the discussion over definitions is the need for clinical services in drug usage. Pharmacists would be well advised to heed the advice of Carlin who, in his presidential address to the ASHP House of Delegates in 1971, said "If the attitudes and skills of practitioners can be changed in the direction of commitment to pharmaceutical service which is both patient and drug therapy oriented - in other words, in the direction whereby pharmacy becomes really clinical - then the adjective 'clinical' will become unnecessary in describing pharmacy practice."[5]

## THE IMPETUS FOR CHANGE

Modern clinical pharmacy emerged during the mid-1960's in the United States, in response to the social needs of the times. The 1960's were years of unrest in the United States, as well as in the rest of the world. Demands for social change were made which were unequaled in the history of the country. Significant events which led to this critical period of history may have begun with World War II. During the war, the United States was strongly unified in direction and purpose. Following the war, the country had increased its strength and influence in the world. In addition to this power was the added effect of the increase in numbers of those entering higher education.

When Russion space technology achievements became known during the 1950's, the United States possessed an impressive number of technically educated people who were soon engaged in creating technological accomplishments superior to any previously known. These efforts contributed to advancements in medical and pharmaceutical areas as well. New electronic monitoring devices were soon in common usage in hospitals, and new drugs were discovered and applied, making some previously crippling and fatal diseases a thing of the past. Although the costs involved in this technological revolution were staggering, it was felt that the security of the nation depended upon space and arms superiority.

Social conditions in the United States, however, were not keeping pace with material advancements. Costs of medical care and drugs rose markedly, and many citizens had no access to health services at all. The civil rights of a large segment of the population were still unprotected by adequate laws. Also, the natural resources of the country were being polluted by industrial wastes. When the United States became involved in the Vietnam War, the dissenting voices of the student population became heard. A virtually open rebellion against the technocratic direction of the country resulted. In addition to the civil rights reforms and environmental protection laws, legislation was passed making health care available to the aged and to others unable to afford it.[6] Therefore, the right to adequate medical care became a partial reality, and human-oriented goals began to receive emphasis.

The health professions, including pharmacy, responded to this social need by becoming more people-centered. A need was seen for the pharmacist to assume his rightful role - as an expert in the use of drugs.

## IMPLEMENTING THE CLINICAL PHARMACY CONCEPT

Clinical pharmacy is committed to improving the quality of drug utilization by changing the traditional behavioral pattern of the pharmacist to that of an expert in drug knowledge. Pharmaceutical educators appear to have been the first group among pharmacists to voluntarily take steps to facilitate this improvement. The year following the publication of the report of the Commission on Pharmaceutical Services to Ambulant Patients by Hospitals and Related Facilities, the Pharmacy-Medicine-Nursing Conference on Health Education was held at the University of Michigan.[7] The conference was the contribution of the College of Pharmacy to the University's sesquicentennial observance of its founding. The conference underscored the need for the pharmacist of the future to be prepared to participate in the team delivery of care in a comprehensive health system. "In order to do this," it was stated, "pharmacy service must become patient-oriented, thereby requiring the development of a clinical component in pharmaceutical education." This was probably the first mention of a clinical experience component for the pharmaceutical curriculum.

In the following year, 1968, the activity of the Curriculum Committee of the AACP "focused primarily on defining the subject area of clinical pharmacy."[8] The following excerpt, taken from its annual report, reflects the changing nature of the Committee's work. "Both the profession and pharmaceutical education seem to be agreed that the pharmacist's role in health care services is expanding to include responsibilities in monitoring drug utilization. His role in providing information on drugs and their use to the public and to other health professionals is also enlarging. On this basis it seems reasonable to anticipate curricular changes designed to provide the pharmacy student with adequate preparation to meet these responsibilities."

The Committee then proceeded to define Clinical Pharmacy in the following manner:

> "Clinical pharmacy is that area within the pharmacy curriculum which deals with patient care with emphasis on drug therapy. Clinical pharmacy seeks to develop a patient-oriented attitude. The acquisition of new knowledge is secondary to the attainment of skills in interprofessional and patient communications."

A second conference that figured prominently in the development of clinical pharmacy was held in San Francisco in 1970 under the auspices of the University of California School of Pharmacy.[9] (Note: This and the Ann Arbor Conference were supported by the Public Health Service of the DHEW.) Although this conference was designed to improve communications between pharmacists and physicians, it was much broader and brought together physicians, pharmacists, nurses, attorneys, hospital administrators and public officials. The discussions and outcomes of this meeting were natural follow-ups to the Michigan conference. "One of the means of acquiring stimuli for innovation is association with members of other professions." "The challenge to pharmacy in the Seventies is the challenge of all health professions -- to place the health care of the nation above the provincial and selfish desires of the individual professions -- to develop the health team as a fact rather than a slogan." Of particular significance to this meeting was the growing realization that health practitioners no longer could discuss the broad problems of health care in isolation. Social pressures were requiring a sharing of responsibilities in the delivery of care if the national goal of comprehensive care were to be achieved.

The San Francisco Conference, in fact, hastened the date for the first "national meeting of representatives of the major health professionals on the subject of interdisciplinary education." The host for this meeting was the Institute of Medicine of the National Academy of Sciences, and the sponsors were the National Center for Health Services Research and the Bureau of Health Manpower Education. The theme of the conference was "Educating for the Health Team." Among the conclusions reached at this meeting was: "The ultimate goal of interdisciplinary education and health care teams must be to better utilize health manpower in order to make available health care that is more comprehensive, effective, and compassionate."[10]

The above conferences are mentioned because they were important events that contributed to the emergence of recognition of changing roles for the pharmacist, and in particular to the emergence of the clinical pharmacy movement. Many other meetings and events also figured prominently in the early evolutionary period, including: the First Clinical Midyear Meeting, ASHP (1965)[11]; the ASHP-AACP Workshop on Clinical Pharmaceutical Practice and Education (1971)[12]; The Task Force on the Pharmacist's Clinical Role (1971)[13]; The Conference to Define Terms "Clinical Pharmacy," "Institutional Pharmacy" and "Group Practice" (1971)[14]; The Study Commission on Pharmacy (1973)[15];

Seventh Edition of the Accreditation Manual, American Council on Pharmaceutical Education (1974)[16]; The Conference on Pharm.D. Programs (1975)[17]; The First International Congress on Clinical Pharmacy Education (1976)[18]; Guidelines for the Clinical Pharmacy Preceptor (1976)[19]; and Incorporation of Clinical Pharmacy into the AACP Teachers' Seminar, which is supported annually by the American Foundation for Pharmaceutical Education.

Although it was through the efforts of pharmacy educators, for the most part, that the ground was prepared for recognition of the clinical pharmacy movement, one must not lose sight of the fact that is was the pharmacist himself who, in many cases, carried on a clinical practice even through the period of upheaval caused by the technological change.

Many of the early experiences in clinical pharmacy were discussed by the authors in a previous paper, [20] but a particularly noteworthy example, deserving repetition here, was the pilot program instituted at the University of California, San Francisco Medical Center, in September 1966.[21] In this experiment, the pharmacist was placed in the clinical setting of a teaching hospital. The program became known as the "Ninth Floor Project," and was staffed on the surgical service on a 24-hour basis. Many advanced concepts of clinical pharmacy were employed: the decentralized pharmacy, the unit-dose concept, the use of pharmacy technicians, a drug information center, and the use of patient drug profiles. The result of this experiment showed clearly that the pharmacist can and did function as a contributing member of the health care team.

Other programs were broadened to include community pharmacy clinical experiences. In early 1967, St. John's University established a clinical pharmacy program consisting of two objectives: (1) to allow the student to observe patients, review charts, and to increase their knowledge of diseases and appropriate drug therapy used; and (2) to involve the students in the work of the Drug Information Center. Adverse drug reactions were particularly emphasized in the program of instruction. Actual study of specimens comparing normally functioning organs with those exhibiting pathological characteristics was undertaken.

Drug information work included the analysis of drug company literature, followed by evaluation of the drugs discussed, principles of literature searching and abstracting, and the use of available resource material.[22] Wayne State University college of pharmacy began a pilot program in 1969 which selected a variety of sites for students to gain experience in clinical pharmacy.[23] In addition to participation in programs at four community hospitals and the county mental health clinic, fourteen community pharmacies were involved as well. That the program was successful in developing clinical pharmacy attitudes is apparent from the reporter's statement: "The principal value of these experiences appears to be that they develop in the students empathy for people, a very important consideration, because this, in turn, urges students to seek out and participate in providing those services which offer a distinct contribution to society. In developing educational programs it is well to keep this goal in mind, because all the clinical knowledge in the world is worthless to a pharmacist in direct contact with the public unless he first has an abiding concern for his fellow man."

## CLINICAL PHARMACY AND HOSPITAL PHARMACY

Clinical pharmacy is frequently identified with hospital pharmacy. It is, of course, understandable how this connection can be made. The hospital environment is one in which the patient population is confined and controlled, laboratory test results are convenient, access to patients' records is available, and drugs are administered directly to the patient by the nursing staff. These factors do provide more convenient facilities and environment conducive to clinical practice, in one sense, but they by no means limit a clinical practice to the hospital alone. People who bring their health needs to a community pharmacy are patients, too, in every sense of the work. And, especially since the drugs they receive will be self-administered, they should at least receive the attention they require in the matter of proper instruction as to using the drug, possible reactions (with both foods and other drugs), and awareness of the effects of the drug based on their past history (patient drug-use profiles).

In Australia, a differentiation has been made between the practice of clinical pharmacy in the hospital and in the community. Naismith suggests that "clinical pharmacy is not just a specialty -- it is a subspecialty of institutional pharmacy. The pharmacist must have ready access to the patient's entire health record to practice comprehensive clinical pharmacy. Therefore, this practice is limited to centralized institutions, such as hospitals, and potentially, the Health Centers which are developing throughout Australia at the moment."[24] On the other hand, he continued, "As opposed to clinical pharmacy practice, clinically oriented pharmacy practice must become the norm of all pharmacy practice if we are to meet the goal we have set for ourselves of becoming drug therapy advisers to other health professions and to the public. Clinically oriented practice reflects an attitude which is fully compatible with every area of pharmacy practice. This attitude requires a concern for the patient -- his needs for pharmaceutical service and how we pharmacists might meet these needs."[25] As practical as the suggestion of "clinical pharmacy" as opposed to "clinically-oriented pharmacy" might seem, it offers a further division of a term already overly defined. Whether clinical pharmacy can be "more comprehensively practiced" in an institutional environment is not the question. If the clinically oriented "attitude" is missing, the practice, in any location, lacks its essential quality.

## DEVELOPMENT ABROAD

The realization of the importance of clinical pharmacy practice has spread from its American origins to world-wide dimensions. Professor D. W. Vere, of the London Hospital Medical College, in relating the contribution of the pharmacist to the interdisciplinary health team, states that nurses are the best observers of adverse drug reactions, and doctors the best ascertainers, but pharmacists are the best collectors and collators.[26] And further: "Doctors could not hope to emulate the drug fact collecting abilities of pharmacists who should provide the knowledge store of up-to-date information." This recognition of the role of the pharmacist as a provider of drug information is, at the same time, recognition of one of the primary clinical pharmacy services, without identifying it as such. At the same conference, Mr. J. P. Kerr, a general practice pharmacist, provided an even more significant clue as to the need for clinical pharmacy in the British medical establishment:[27] "The personal contact with the patient is perhaps one of the most fundamental roles of the pharmacist."

In community practice in Britain there has also been recognized a need for drug information services similar to those which have been employed in hospital environments. The future role of the community pharmacist in Britain will include "...giving advice to doctors regarding the composition and pharmacological action of a wide variety of different drugs and preparations of drugs."[28]

The providing of primary medical care by community pharmacists has also been studied by pharmacy educators in Britain.[29] A team of researchers visited 183 pharmacies to assess the quality of primary care offered by pharmacists, the validity of advice given to patients, and the appropriateness of medications recommended. It was found that the advice was entirely satisfactory on 20 percent of the visits, reasonably sound on 30 percent, but quite inappropriate on 18 percent. Of the 70 different medicines purchased, on the pharmacist's recommendation, 68 percent were considered reasonably appropriate, which was considered to be comparable to general medical consultations. The researchers see the pharmacist's role in primary medical care as a "filter between patients and general practitioners, in some circumstances."[30]

A Canadian study[31] concerned with primary care in the community pharmacy also showed the pharmacist's contribution to be valuable. Five representative pharmacies were selected in various locations in London, Ontario. The most common ailments presented to the survey pharmacist, comprising 60 percent of the total, were: 1. Upper respiratory tract problems; 2. Stomach and bowel problems; 3. Pain; 4. Vitamin-related inquiries. The major courses of action available to the pharmacist in handling these complaints were: 1. Recommending an OTC drug; 2 Referral to medical care; and 3. Other (including "reassurance," information, and other nondrug advice).

The first course of action was followed in 80 percent of the cases; 12 percent of the cases required the second course of action; and 8 percent required the third. The study further revealed that three of the five pharmacists surveyed were providing 20 or more primary care services per day. When one considers a total of 47 pharmacies in the city of London, Ont., this indicates an extensive amount of primary care provided to community pharmacy clients.

Recent government action in Canada has resulted in the passage of the Health Disciplines Act of Ontario.[32] One of the provisions of the Act requires that pharmacists communicate with patients regarding the sale of certain OTC medications. The drugs selected can only be purchased in pharmacies, and before being sold the pharmacist must inform the patient concerning their use. Although this indicates a direction towards clinical pharmacy by legal mandate, the question of remuneration for the pharmacist's time is still unresolved. A requirement for making patient profiles mandatory is also under consideration by the Ontario College of Pharmacists. This will result in increased pharmacist/patient communication. The voice of the consumer is also being heard by Canadian pharmacy. The demand is raised by consumer groups that pharmacists discuss with patients some aspects of their medications and the benefit or toxicity that is likely to occur from ingestion of such medication.

Clinical pharmacy education in Canada developed similar to the way it did in the United States. The University of Toronto reports that their first program of clinical pharmacy courses was begun in 1969.[33] At this time an elective course was offered to students concerned with reading patient's charts. The program has now increased in depth, and all students now receive 100 hours of clinical pharmacy instruction. "The general objective of the program is to expose the students to clinical situations making them more aware of total patient care and those aspects which can be improved upon by the intervention of the clinically oriented pharmacist."[34]

The tendency to associate clinical pharmacy solely with hospital pharmacy does not remain unchallenged within the profession. According to Professor J. Thomas of the University of Sydney,[35] "Hospital pharmacy will always employ a minority of pharmacists, and with the development in health-care delivery systems being more and more oriented towards prevention and community care rather than acute hospital and acute medicine, I feel it is back in community pharmacy where the action is going to be." He further sees a weakness in the highly trained Pharm.D. specialist concerning his lack of authority to use drugs, and that he can only use his knowledge if asked to do so. In the matter of the community pharmacist's role, Thomas sees it consisting mainly of transmitting information and advice to patients, and the educating of clinical pharmacists in any environment must include an understanding of disease processes and a working knowledge of physiology.

The importance of the dissemination of drug information as a function of clinical pharmacy is recognized in Swedish pharmacy practice.[36] This function is centralized to serve military hospitals, in addition to the existence of drug information centers at various city hospitals. These services are computerized, and details and literature searches are made available. In conjunction with drug information services, the drug committees of various hospitals ensure that the therapeutically most effective drugs are supplied to the hospitals and that they are used under safe and rational conditions.

## COMMENTS

Ten years have passed since the first evidence of the use of the term clinical pharmacy appeared. That the term has had a generic meaning to some and a specific meaning to others is quite clear. It is also obvious that the term has been used carelessly in many instances, a fact that in itself has clouded the ultimate value it may have to the profession. Experiences to date are all too clear in their mandate to the profession to define its terminology, and encourage its members to be precise in its use. Use of such terms as patient orientation, patient-care orientation, patient-related attitude and similar terms to describe clinical pharmacy should be discouraged because they are ambiguous and nonspecific.

An environment and a facility can be described as clinical without misleading or confusing an audience. Any facility where pharmacy is practiced and maintained in a hygienic, orderly, professional atmosphere conducive to efficient health care should be worthy of description as a clinical facility. Unfortunately, the environment in which pharmacy is practiced in many outlets is unprofessional, unhygienic and commercialized, and association of the term clinical with these must not be condoned. Association of the term clinical with a role for a pharmacist should be clarified. The term should be defined first as a characteristic that is common to the practice of pharmacy in all its undifferentiated roles, and one that graduates of all entry degrees programs to the profession should have acquired.

If one analyzes carefully the minimum objectives of the first professional degree in pharmacy in the report of the Study Commission on Pharmacy,[3] he concludes that one of the skills that should be developed is a clinical skill. One cannot read seriously the Commission's report without concluding that society's needs, pharmacy's failure in the past, and pharmacy's hope for the future lie with drug knowledge, its dissemination and use. The basic clinical skill for all pharmacists, accordingly, must be related to drug knowledge and information. Therefore, the generic clinical skill can be defined as a capacity to understand, communicate to others, and use drug information in the care of patients. This generic skill or competency is common to all of the roles of pharmacy practice. For those pharmacists whose roles become differentiated by the mastery of additional knowledge and the acquisition of new practice experiences the character of this clinical skill will change. If special clinical skills for the pharmacist are developed, they will be justified only to the extent that they fill existing unmet needs and in a manner that is both acceptable to the recipients of his services and is cost effective in the system that finances the cost of health care.

In conclusion, two paragraphs from the paper referred to previously (The Evolution of the Clinical Pharmacy Concept) may provide an appropriate conclusion to the present discussion.

"There exists a natural three step sequence that the pharmacist instinctively follows once he receives a physician's order for a medicine, which focuses first on the pharmacist, and the quality of his performance, second on the medicine, and the knowledge and skill that its preparation requires, and third on the patient, to whom he administers the medicine or to whom he distributes it. This order of events has become distorted. The normal sequence seems to have been interrupted at the second step and the pharmacist's terminal focus has become the medicine, itself, representing as it is, the fruit of his own labors. Interestingly enough, this same analogy can be applied to medical practice and the physician, and the shift of his focus from the patient to the disease itself. Quite likely, this is a universal failure of health care delivery in our times, and appears to be applicable to all health care providers and institutions.

"From this perhaps overly simplified explanation, it is easy to interpret what the introduction of the clinical pharmacy concept in these times is doing: it is beginning to realign the historic scope of concern for a client by the pharmacist, again focusing his ultimate concern on the recipient of his service; it is giving a renewed visibility and increasing importance to the third step in the natural sequence. In so doing the pharmacist is not abrogating his responsibilities as a pharmaceutical scientist, because it is his mastery of the body of knowledge, broadly chemical and biomedical, and uniquely pharmaceutical in nature, that justifies his services to society."

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# CLINICAL PHARMACY PRACTICE - WHAT IT IS AND WHERE IT IS GOING

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It has always seemed somewhat paradoxical to me that the concept of clinical pharmacy was developed in an English-speaking country because the soil for clinical pharmacy practice in the community is so much more fertile in non-English speaking countries. I cannot believe there are many at this international meeting who have not considered that it is only in the English-speaking countries that anyone can open a pharmacy or drugstore anywhere he pleases at anytime he wantsto and can dispense prescriptions and medicines and in the same location sell all types of merchandise without restraint, from motor accessories to hardware to shoes and clothing. Despite this pattern of practice, there were other elements which allowed the seeds of clinical practice to germinate.

As this is being written, I have not seen Dr. Brodie's account of the development of clinical pharmacy but I believe some of the significant factors include the following. In the 1950s a large number of hospital pharmacists obtained advanced professional degrees, served a residency in hospital pharmacy and demonstrated what a group of highly motivated, well trained pharmacists could accomplish in a health care setting. Later, the fundamental studies on medication errors made by McConnell and Barker at Florida showed that many more errors were made in the administration of medications than anyone had suspected. As a result of these studies, more and more pharmacists started to venture out of the pharmacy to the patient care areas and to become much more closely involved with the physician, the patient and the nurse. A bit later, articles began to appear describing adverse reactions to drugs and calling attention to the relationship between the number of drugs given to patients and the incidence of reactions. A little later the drug interaction literature began to appear. During this same period the sciences of biopharmaceutics and pharmacokinetics blossomed and they were shown to be directly applicable to patient care where they could be used to promote the safe and effective use of medicines in people. The combination of each of these developments has been very important in the flowering of clinical pharmacy.

Another major source of strength for clinical pharmacy has been the incorporation of practicing pharmacists with advanced degrees into the faculties of schools of pharmacy to serve as teachers and role models for students. The colleges deserve high praise for this.

One can perhaps explain its significance by relating it to the role of the practicing physician in medical education. In medical schools, most of those who teach the basic sciences such as anatomy, physiology, microbiology, biochemistry, etc. hold the Ph.D. degree. These people provide the basic scientific education for the medical students. However, it is practicing physicians, most of whom have only their basic M.D. degree, who teach and train the medical students to become physicians during their clinical years. For example, the chief of medicine daily sees patients, he lectures to medical students, interns and residents and instructs them by precept, he conducts research, contributes to the literature and, most importantly, serves as a role model for all of his students. By adopting this model of education, the colleges of pharmacy have greatly increased their strength and relevance.

## LEVELS OF PRACTICE

I will now turn to my assigned topic "Clinical Pharmacy Practice - What It Is and Where It Is Going" and indicate my judgment of the several levels of clinical and nonclinical pharmacy practice as shown in the first Table. As you will recognize, many of these judgments are arbitrary and all are open to modification. I have listed five levels of practice. The criteria I used was my judgment as to whether 90 percent of the people at one level could perform 90 percent of the responsibilities of the next higher level. If they could not, then there are separate levels; if they could, I merged the levels. For example, I believe there is a significant difference between the levels of practice of a generic pharmacist and a clinical pharmacist generalist and that 90 percent of the present generic pharmacists cannot carry out 90 percent of the responsibilities of the clinical pharmacist generalist. In the same way, I believe that 90 percent of the clinical pharmacist generalists cannot carry out the responsibilities of 90 percent of the pharmacotherapeutic specialists or applied pharmacologists. Some of you will disagree. You will insist that you train all of your Pharm.D.s to the level of the pharmacotherapeutic specialist. This may be true of a few programs. But my judgment is based on a general impression of all programs. Furthermore, until levels of competency are determined and applied, any graduate can continue to claim any level of competency in professional practice he chooses.

The need for a relatively small number of clinical scientists has been pointed out by the Millis Commission.[1] A clinical scientist is one who is equally skilled and trained in a science and in pharmacy practice; he is compared to a physician who is equally at home at the patient's bedside or in the laboratory. I can think of a large number of physicians who qualify as clinical scientists; by far the greatest number of them have only their basic professional degree, while a few also hold a Ph.D. Of pharmacy's basic scientists, the only one I can think of who could have significant patient involvement would be those in biopharmaceutics and pharmacokinetics and, to a lesser extent, pharmaceutics (sterility, compatibility, stability) and perhaps pharmacology and toxicology. I cannot imagine the usual analytical chemist, medicinal chemist, pharmacognosist or most persons in pharmaceutics or pharmacy administration having significant direct contact with patients. On the other hand, I am not at all implying that the facts and concepts taught in these disciplines do not have relevance to clinical pharmacy practice. They most certainly do. But this does not make the teacher "equally at home at the patient's bedside or in the laboratory."[1]

If we relate the clinical scientist in medicine to the clinical scientist in pharmacy what do we find. First that the large majority of physicians who are clinical scientists possess only their basic professional degree; a few also have a research degree. Second, physicians with this background perform significant research in such fields as lipid research, cancer research, hematology, hypertension and many others. Third, the research team is almost always multi-disciplinary and numerous specialists contribute. Fourth, the physician, since he bears the chief responsibility for the patient, is the leader of the research team. It would be my judgment that clinical scientists in pharmacy will develop in somewhat the same manner. A number of those who receive good training in the basic sciences, who have the appropriate motivation, who possess excellent clinical training and who have a proper health care setting for research involvement will become clinical scientists without too much additional formalized effort. This group will elicit from the basic scientists the knowledge or facts required to link basic science and pharmacy practice. This may lead to an analysis of the competencies involved in certain clinical roles, which is the basis for the Millis Commission's recommendation - and again it may not. It should lead to advances in patient care, but I am not certain whether these would call for new competencies beyond those achieved - it may, and again it may not.

In the early days of clinical pharmacy education, I attempted to conceptualize what a clinical pharmacist was and thought of him as an applied pharmacologist. I thought of the clinical pharmacist as being a person who, in addition to his basic pharmacology, had taken courses in pharmacology and therapeutics with medical students, courses in which he would receive a great deal of therapeutics. I thought of him as having graduate level courses in biostatistics, pathophysiology, biopharmaceutics and pharmacokinetics, and the sociology of health care. These courses plus his general educational background in microbiology, pharmaceutics, formulation, etc., plus suitable clinical training such as a residency or clerkship would produce one of the most drug knowledgeable people on the health team. Some people don't like calling the clinical pharmacist an applied pharmacologist because they think it might antagonize clinical pharmacologists. Thus, I also think of the clinical pharmacist as a pharmacotherapeutic specialist. The important consideration, I believe, are his knowledge of therapeutics and the actions of drugs in humans. In the preface to the first edition of Applied Pharmacology which the British physician, A. J. Clark, wrote more than fifty years ago, he said that his objective was "to give an account of the direct scientific evidence for the therapeutic action of the most important drugs, and to demonstrate the importance of this knowledge in the clinical application of drugs."[2] This is essentially the objective of the high level clinical pharmacist whether you call him a pharmacotherapeutic specialist or an applied pharmacologist.

The clinical pharmacy generalist is a person who is not as well grounded as the applied pharmacologist in pharmacology, therapeutics, biostatistics, biopharmaceutics, or pharmacokinetics does not have his clinical experience. Still he has a sufficient background to be a valuable member of the health care team. As his title implies, he is a generalist with a broad range of drug knowledge. The differences between the pharmacotherapeutic specialist and the clinical pharmacy generalist will be illustrated a bit later in slides depicting their roles.

There are hundreds of what the Millis Commission describes as generic pharmacists practicing in community pharmacies and in hospital pharmacies. Some of these are involved in a high percentage of professional activities and are engaged in daily patient-physician contacts and perform many important clinical services for patients and the health care team. It is my expectation

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that these generic pharmacists will soon merge with the clinical pharmacy generalist so that the general level of the profession will be raised.

On the other hand there is a substantial number of generic pharmacists who are involved in a low percentage of professional activities and perform few if any clinical functions. In my opinion, this group of generic pharmacists should be merged with trained pharmacy technologists who can competently perform 90 percent of what this group of generic pharmacists now do.

## ROLES FOR CLINICAL PHARMACY PRACTICE

At the heart of all the roles played by clinical pharmacists in a variety of settings are his primary care roles, some of which I have outlined in Table 2. The clinical pharmacist's principal function may be characterized as responsibility for all drug related activities. One of the most important of these is to exercise drug-use control which Brodie has defined "as that system of knowledge, understanding, judgments, procedures, skills, controls and ethics that assures optimal safety in the distribution and use of medication." "This definition," says Brodie "relates professional function to patient welfare in the form of drug safety; it is patient oriented. It is the heart of the body of practice ..."[3] It is important to recognize that Brodie was not speaking of dispensing when he discussed drug-use control. He had this to say about dispensing. "There are those who believe that pharmaceutical dispensing is the mainstream activity of pharmacy service. To those who accept this reasoning, the following statement is pertinent and quoting the Mirror to Hospital Pharmacy Brodie continued, "...the dispensing function of the pharmacist, while important and even vital for patient care, is essentially a superficial practice of the profession which, by itself, does not utilize knowledge or skills sufficiently basic to merit professional recognition to the depth that lies within the grasp of pharmacists."[3]

Under ideal circumstances and in the proper setting, I am certain that all of the 17 responsibilities listed could be carried out by most competent clinical pharmacy generalists. Certainly this is true of the vast majority of them, while some such as the management of patients with acute and chronic diseases would most likely be carried out in an institutional setting.

I have outlined my concept of the roles of the clinical pharmacy generalist and now I will indicate how the pharmacotherapeutic specialist differs. This is shown in Table 3. In essence, I believe this is a separate category because in my opinion 90 percent of the clinical pharmacy generalists cannot competently perform 90 percent of the roles of the pharmacotherapeutic specialist. Generally speaking, the pharmacotherapeutic specialist has a significantly better background in pharmacology, therapeutics, pharmacokinetics and biostatistics than does the clinical pharmacy generalist. I believe that these differences will be demonstrated when a program to evaluate competency is completed by the APhA and AACP.

The roles of the generic pharmacist - pharmacy technologist are shown in Table 4. I believe it is fair to say that a significant number of pharmacists perform these roles 90 percent of the time. I believe it is also fair to say that 90 percent of trained pharmacy technologists could competently perform 90 percent of the tasks of the generic pharmacists. Pharmacy would gain in strength and stature if these two were merged into pharmacy technologists.

I believe it is also fair to say that a large percentage of the general public views the roles of the pharmacist as limited to those of the generic pharmacist as shown in Table 4. Mr. Chief Justice Burger recently had this to say about the role of the pharmacist. "The Court notes that roughly 95 percent of all prescriptions are filled with dosage units already prepared by the manufacturer and sold to the pharmacy in that form ... In dispensing these items, the pharmacist performs three tasks; he finds the correct bottle; he counts out the correct number of tablets or measures the right amount of fluid; and he accurately transfers the doctor's dosage instructions to the container. Without minimizing the potential consequences of error in performing these tasks or the importance of the other tasks a professional pharmacist performs, it is clear that in this regard he no more renders a true professional service than does a clerk who sells lawbooks."[4]

Mr. Justice Burger implies that pharmacists use little or no professional judgment in exercising their profession and, again, I believe this is a view held by the public at large. Burger continues, "Attorneys and physicians are engaged primarily in providing services in which professional judgment is a large component, a matter very different from the retail sale of labeled drugs already prepared by others ... I think it is important to note also that the advertisement of professional services carries with it quite different risks than the advertisement of standard products. The Court took note of this in ... upholding a state statute prohibiting entirely certain types of advertisements by dentists."

"The legislature was not dealing with traders in commodities, but with the vital interest of public health, and with a profession treating bodily ills and demanding different standards of conduct from those which are traditional in the competition of the market place. The community is concerned with the maintenance of professional standards which will insure not only competency in individual practitioners, but protection against those who would prey upon a public peculiarly susceptible to imposition through alluring promises of physical relief. And the community is concerned in providing safeguards not only against deception, but against practices which would tend to demoralize the profession by forcing its members into an unseemly rivalry which would enlarge the opportunities of the least scrupulous."[4]

Thus, we plainly see that the public in general, in views expressed by the Supreme Court, do not know of the professional services which can be offered by the pharmacist. And why is this? In my opinion it is because most pharmacists with whom the public comes in contact with limits their service to the dispensing function and they practice in an environment which by the standards of other health professions lacks dignity and professionalism.

## TEACHING - PATIENT SERVICE ROLES IN A VARIETY OF SETTINGS

The various levels of pharmacy and clinical pharmacy practice I have described are carried out in a variety of settings under a variety of circumstances. Putting the clinical scientist aside for the moment, we find the clinical pharmacy generalist and the pharmacotherapeutic specialist performing teaching functions in a variety of settings. Since there is at present no evaluation of competency we probably find these two groups intermixed much more at present than they will be in the future.

In my opinion, the clinical pharmacy generalist can practice in a large variety of settings including primary care, psychiatric and mental health institutions, hospital and community practice, ambulatory clinics and others.

The pharmacotherapeutic specialists will most likely be teachers in medical and pharmacy schools, work with physicians in teaching hospitals without a college of pharmacy, be deeply involved in the treatment of chemical toxicity, be involved with the department of clinical pharmacology in drug evaluation programs and similar situations in which an excellent knowledge of pharmacotherapeutics is essential.

## TEACHING ROLES WITH LITTLE PATIENT RESPONSIBILITY

Some schools of pharmacy employ a person to teach clinical pharmacy in the same way they employ a professor to teach medicinal chemistry, that is without any responsibility for professional practice. Since they are not involved in day-to-day clinical pharmacy service for patients, they can teach the student about clinical pharmacy but are poor role models since they never practice it themselves. There are undoubtedly numerous reasons for this but surely one of the main reasons must be such a high teaching load that the person has no time for professional practice. Perhaps in some cases the clinical pharmacy professor himself resists professional practice because it is so much more difficult than teaching because he is forced to maintain his knowledge at a high level if he is to practice successfully, while the demands are not so great if he merely teaches. In response to a survey[5] conducted in 1974, a majority of clinical pharmacists believed they should be engaged in practice 50% or more of their time to maintain their competency as shown in Table 6. If clincial pharmacy is ever to become a creditable practice it must have suitable role models to emulate. It seems to me that the nonpracticing clinical pharmacist is about the same type of role model as a nonpracticing physician would be, except I don't believe you could find a nonpracticing physician teaching medical students in a school of medicine.

## TEACHING - PATIENT SERVICE ROLLS

There are a number of clinical pharmacists who perform teaching-patient service roles in medical schools, pharmacy schools and others as shown in Table 5. Probably the outstanding example of clinical pharmacists teaching in medical schools is the Docent Clinical Pharmacist who is part of the teaching-patient care team at the University of Missouri. I would consider most all of these clinical pharmacists teachers as pharmacotherapeutic specialists. In a survey Whitney and I did in 1974, we found that 38 percent of clinical pharmacists in our sample held appointments in medicine, 23 percent in pediatrics, 15 percent in clinical pharmacology and 19 percent in other clinical departments.[5] In most cases these appointments did not carry additional compensation. Principally they involved a few formal lectures to medical interns, residents and students plus considerable informal teaching.

Many colleges of pharmacy make a serious effort to have their clinical faculty involved directly with patient care. Results of a survey done in 1974 are shown in Table 7. Thirty faculty members in 19 hospitals had fewer than 500 hours a year patient service-related contact, while 63 faculty members in 13 hospitals had more than 1500 hours of such contact, while 24 percent had between 500-1000 hours a year. Of course, it is probably that much of the patient contact time also involved teaching.

The Veterans Administration is making a significant contribution to clinical pharmacy education through the appointment of about 15 Clinical Pharmacy Teaching Coordinators all of whom have an advanced professional degree and work with the VA residents and volunteer their teaching services to a college.

There are a number of patient oriented roles for clinical pharmacists in institutions not associated with colleges of pharmacy. Some of the most intensive patient involvement is in the Indian Health Service where clinical pharmacists now provide care for about 10 percent of all ambulatory patients and in at least one installation to more than 50 percent of patients.

The following is taken from Captain Brand's 1975 Report and will indicate the scope of the patient care provided by pharmacists in the Public Health Service.

"Ambulatory patients may elect to see the pharmacist instead of the physician for certain acute illnesses in 76 Service Units as compared to 71 last year. Using established guidelines, the pharmacist obtains subjective and objective data which includes patient symptoms, vital signs and laboratory tests as indicated. The pharmacist evaluates the data and makes a judgment as to whether to treat the patient himself or refer the patient to a physician.

Long-term drug therapy for ambulatory patients with chronic diseases is monitored and evaluated by the pharmacist in 60 Service Units (as compared to 47 last year). Guidelines for this activity have been established by the medical and pharmacy staff at 37 facilities."[6]

Although not associated directly with a college of pharmacy, I consider the clinical pharmacists at The New York Hospital as pharmacotherapeutic specialists who play an important role in the education of health professionals including physicians, nurses and pharmacists. The stated purpose of the Coordinator for Inpatient Clinical Pharmacy Service is "To coordinate the pharmaceutical distribution and clinical services necessary for safe and appropriate use of drugs for patients care."[7] The stated objective for the Assistant Director for Education and Information at The New Nork Hospital is "To plan and direct all training and education within the scope of the Pharmacy Department. To develop drug information services for the use of the physicians, pharmacists and nurses to provide patient care."[7]

Time does not permit discussion of the characteristics of other sites except I do want to reiterate that the service in all these settings are given by either clinical pharmacy generalists or pharmacotherapeutic specialists with the drug information specialists having additional training in drug information sources and their evaluation.

This brings us to community practice. The overall types of community pharmacies are classified in Table 10. The number and types of community pharmacies in the United States are shown in Table 11. The variations in the numbers and retail drug volume of community and chain store pharmacies 1965-1975 are shown in Table 12. While this table is based on chains of 2 or more stores and perhaps the percentages are inflated, nevertheless, I believe it indicates the rapid growth, development and strength of chain drugstores in the United States.

This brings us to the community practice roles where at present there seems to me to be principally two types of generic pharmacists practicing -- one with significant clinical roles and the second with little or no clinical role. The first type would be characterized by the pharmacies of Donald Baugher of Illinois and Eugene White the family pharmacist from Virginia. These pharmacists and many others like them are offering a patient oriented service which would unquestionably warrant the services of a clinical pharmacy generalist. Unfortunately these are a small minority. In addition, there are a fairly large number of pharmacies which offer pharmacy service, medicines, cosmetics, and related health supplies plus a limited number of unrelated items. In these pharmacies the atmosphere is professional and the pharmacist is readily available to talk to clients. These pharmacies would also warrant the services of a clinical pharmacy generalist.

There are far more generic pharmacists practicing in institutions who project the images of pharmacy to the public. The pharmacists in these stores usually do not talk to the public, are not readily available to the public and, for the most part, limit their work to the dispensing of a drug product which is transferred to a clerk who gives it to the patient. I have a difficult time seeing the need for clinical pharmacy generalists in a pharmacy of this type, unless significant changes are made.

Thus we have in community pharmacy a continuum from the dignified, highly professional pharmacy to the raucous, repugnant, commercialized jungles which characterizes many large merchandizing chain stores and independent stores which seem to emulate them.

Some leadership group in the profession should assemble representatives who, after deliberation, would draw a line on the continuum between the professional pharmacy and the other extreme, characterized by many large chain stores, and say "Beyond this the profession will be uncooperative; these items are not appropriate for sale in a pharmacy; it is inappropriate to advertise these items under the banner of a pharmacy or drugstore; this place is inappropriate for the practice of pharmacy." What cannot be done by law, can perhaps be accomplished by moral suasion. Twenty-five years ago The Pharmaceutical Survey had these prophetic words to say: "vigorous offensive action is clearly indicated if (pharmacy) is to maintain a recognized ranking position among the health professions ... after all has been said and done, it may be concluded that the outstanding factor determining the future of the profession of pharmacy is fundamentally moral in nature. The profession must contain a far greater proportion of members who are ever sharply jealous of the high reputation of the profession and who, by energetic cooperation, are determined ever to protect that reputation."[8] What better time for action than now as the profession lays plans for the future practice of clinical pharmacy in the community as well as the institution.

There is one highly important change which I believe the profession should make in order to improve the image of pharmacy. That is to take a leaf from our Canadian neighbors and prohibit the use of the terms "pharmacy, drug, prescription" etc. in advertisements for such general merchandise as auto accessories such as fan belts, automobile batteries, household goods such as cooking utensils and hardware, clothing, bicycles and similar items. Thus, the public would not see ads such as the one by Dart Drug advertising automobile batteries and motor oil under the banner of pharmacy nor the one by Drug Fair advertising clothing and linens. These items should not be advertised under the banner of pharmacy or drugstore. For example, some of Sears department stores have an optical department. However, ads for all merchandise sold by Sears are not offered for sale under the banner of Sears Optical Department.

Many department stores such as J.L. Hudson in Detroit have a pharmacy. Yet when they advertise their merchandise they do not do so under the banner of Hudson's Pharmacy or Hudson's Drug Store. No, it is only the large merchandising chain drug stores which do this and thereby stand as a cancer on the body of pharmacy where it will remain until this practice is stopped. If general merchandising corporations must include a pharmacy in their operation let them do so, but pharmacy should protest vigorously when a wide variety of products are advertised under the pharmacy banner. The profession could stop this practice if it would unite and attack.

I want to make a comment about OTC medicines. The profession should appreciate that the present drug distribution system for OTC drugs operating in most community and chain pharmacies where the client selects his OTC medication without any involvement on the part of the pharmacist and pays a checkout person for it, effectively blocks the pharmacist from playing an important role in this aspect of health care. On the other hand, OTC drugs constitutes about 50 percent of the medication used by people. The pharmacist's role in selection of OTC drug products has been studied by Wertheimer,[10] Knapp,[11], Linn and Davis [12] and others all of whom found the performance of pharmacists extremely poor.

Others have studied the same question and found that pharmacists had little or no interest or concern with OTC drugs. It is not enough for colleges to offer courses in OTC medications. They must take more leadership in seeing that at least selected OTC drugs are sold under conditions that require involvement by the pharmacist. Again we would look to our Canadian colleagues for guidance and note what they have done in several of their provinces to involve the pharmacist in the sale of a wide variety of drugs.[9]

## PROGNOSTICATIONS

Our Chairman asked me to prognosticate about the future of clinical pharmacy and I am happy to do this knowing that some predictions have a way of not coming true while others do. First let me say a few words about clinical pharmacy education and training. In my opinion clinical pharmacy education and training will change dramatically in the immediate future by which I mean the next five years or so. Within that time I do not believe we will continue to educate pharmacists; rather we will educate clinical pharmacists. The practice of pharmacy will cease to exist, a victim of semantics. Every pharmacist will be awarded a Pharm.D. Many pharmacists now in practice will be awarded Pharm.D. degrees by their alma mater either for completing some type of a continuing education program or en masse, as the schools of law have awarded the J.D. degree.

Thus in a very short time I predict that the character of the Pharm.D. will change from the pharmacotherapeutic specialist or clinical pharmacy generalist to something between the generic pharmacist and the clinical pharmacy generalist. Thus the stature of the degree will be lowered. We will no longer attract to the Pharm.D. only the highly motivated, clinically interested student; rather, all students will be granted the Pharm.D. regardless of their interests. Unless what the pharmacist does changes significantly, there will be a great increase in frustration among pharmacists.

I predict the establishment of a large number of postgraduate clinical pharmacy training programs both at health centers with a college of pharmacy and at those without a pharmacy school. These sites will train the pharmacotherapeutic specialist or applied pharmacologist. This person will be the clinical pharmacy teacher of tomorrow and I believe the possibility is good that he will receive at least part of his training in departments of clinical pharmacology of medical schools where he will participate more actively in the education of medical students, interns and residents. Few will practice in other than health science settings. An equal or greater number of clinical pharmacy generalists will also teach.

I predict that essentially all colleges of pharmacy not associated with a health science center will establish clinical campuses at conveniently located health centers, not necessarily health science centers. Students will live near these centers for approximately the final year of their education in order to round out their clinical experience which will have begun elsewhere. The clinical faculty will function principally at these centers.

Will preparing all pharmacists as clinical pharmacists be good or bad for the profession? I have mixed feelings. If the pharmacist continues to practice as he does today, it will be an enormous waste. But it does not have to be. In the process we should train a pharmacist to perform at a significantly greater clinical level and perhaps this is the only way that pharmacy practice can change. My personal reservations are related to the settings in which the community pharmacist functions which to me seem inappropriate sites to render a health service to people. However, I appreciate that few American pharmacists have any desire to change them, either that or they feel the attempt is hopeless failing to recognize what can be accomplished by concerted action. Yet I feel that the profession will not advance unless a change is made. The colleges have a big stake in bringing about a change.

I predict that eventually the colleges and the members of the profession itself will recognize that trained pharmacy technologists can perform 90 percent of the tasks now done by many, many generic pharmacists who emphasize their dispensing role. In some ways it seems sad to me to see the colleges putting out more and more overtrained pharmacists to perform the tasks that are carried out with competence by dispensing assistants in other countries. We don't need a clinical pharmacy generalist to replace all the pharmacists we have practicing today. What we need and what I believe society will soon demand is a relatively small number of clinical pharmacy generalists and a large number of trained pharmacy technologists and I am not talking about those faceless, mindless "pharmacy aides" that so many talk about. Rather, I speak of a person educated and trained to the level required to carry out the dispensing function. But I predict that it will require almost a decade for the profession to accept this level of person. In the meantine, individual states and individual organizations will continue to recognize and establish technical programs of various types without an input from the colleges. I hope the awakening is not too late, but I fear it may be.

I predict that the health care system will soon have a number of people authorized to diagnose and prescribe under certain circumstances. In the proper setting, there is no reason why the pharmacist cannot be one of these. If the practitioner is truly a clinical pharmacy generalist and is competent to do the things I outlined, the public will come to him in great numbers. The competition for these diagnosing and prescribing roles will be severe and a test for competency essential.

I predict that the competency requirements now being drafted will greatly expand and change the role of continuing education in pharmacy and that within five years the majority of states will make continuing education compulsory for relicensure.

In closing may I say that I believe that the concept of clinical pharmacy is the freshest, most invigorating, challenging and exciting breeze that has blown across the horizons of pharmacy in any land for generations. I hope that its message will ring loud and clear from this First International Congress of Clinical Pharmacy Education in this Bicentennial year to all parts of the world and that it will stand as a contribution from the new world to the old world and to the third world for the rejuvenation or renaissance of pharmacy practice everywhere.

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## Table 1

Levels of Pharmacy Practice

Clinical Pharmacists

1. Clinical Scientists
2. Pharmacotherapeutic Specialist or Applied Pharmacologist
3. Clinical Pharmacy Generalist

Generic Pharmacist

4. Generic pharmacist involved in a high % professional activities, performs clinical functions and has daily patient-physician contacts

Generic Pharmacist - Pharmacy Technologist

5. Generic pharmacists involved in a low % of professional activity, performs little or no clinical functions and has little contact with patients or physicians.

90% of trained pharmacy technologists can perform 90% of what this generic pharmacist does.

Table 2

Roles For Clinical Pharmacy Generalist

Primary Care Roles

Responsibility for Drug Related Activities

(1) Supervises all drug distribution activities for drug use control and patient safety.
(2) Selects drug products.
(3) Monitors patient's response to drugs utilizing patient medication profile and other resources.
(4) Takes patient's medication history of drugs recently taken and any adverse reaction therefrom.
(5) Detects and diagnosis adverse drug reactions and drug interactions.
(6) Counsels patients on use of drugs to assure compliance.
(7) Advises patients on selection of OTC drugs.
(8) Helps establish dosage regimens for patients.
(9) Ability to evaluate the drug literature.
(10) Promotes rational drug therapy by physicians
(11) Performs drug utilization review.
(12) Provides health care education to public.
(13) Integrates the psycho-socio-economic aspects of patient care into practice.
(14) Prescribes for mild, self-limiting diseases.
(15) Supervises management of patients with acute and chronic diseases.
(16) Detects and overcomes incompatibilities and instabilities in drug mixtures.
(17) Directs compounding of drug preparations to meet specific patient requirements.

Table 3

Roles for Pharmacotherapeutic Specialist

Primary Care Roles

Responsibility for Pharmacotherapeutic Activities Related to Therapy

(1) Can perform all roles cited for Clinical Pharmacy Generalist.
(2) Given a patient's diagnosis, designs a therapeutic regimen based on patient-specific parameters.
(3) Establishes therapeutic goals.
(4) Establishes therapeutic endpoints.
(5) Designs therapeutic alternatives.
(6) Applies indepth pharmacokinetic knowledge to design dosage regimens.
(7) Manages treatment of patients with chemical toxicity due to poisoning, etc.
(8) Ability to critically evaluate therapeutic drug literature.

## Table 4

### Roles for Generic Pharmacist - Pharmacy Technologist

(1) Interprets Rx; contacts M.D. for clarification, if necessary.
(2) Selects drug from stock or compounds Rx as required.
(3) Places appropriate quantity of drug in container.
(4) Types label with appropriate directions.
(5) Checks work for accuracy.
(6) Transfers Rx for presentation to patient.

## Table 5

### Roles for Clinical Pharmacy Practice

Teaching Roles With Little Patient Responsibility

(1) In pharmacy schools

Teaching-Patient Service Roles

(1) In medical schools
(2) In pharmacy schools
(3) In other professional schools
(4) V A Clinical Pharmacy Teaching Coordinators
(5) Other settings

## Table 6

### PERCENT OF TIME FOR PRACTICE TO MAINTAIN COMPETENCY

|  | PERCENT OF RESPONDENTS |
|---|---|
| LESS THAN 50% | 20 |
| 50% | 40 |
| MORE THAN 50% | 40 |

MEAN 55% MODE 50% MEDIAN 50%

## Table 7

## PATIENT CONTACT BY CLINICAL FACULTY

| HOURS/YEAR CONTACT | MINIMUM HOURS/YEAR CONTACT | NUMBER HOSPITALS | NUMBER FACULTY |
|---|---|---|---|
| 500 | - | 19 | 30 |
| 500-1000 | 96,000-192,000 | 8 | 24 |
| 1000-1500 | 154,000-231,000 | 7 | 22 |
| 1500 | 1,228,500 | 13 | 63 |

## Table 8

## Roles for Clinical Pharmacy Practice

Patient Service Oriented Roles

(1) Indian Health Service Models
(2) New York Hospital Model
(3) Williamsport, Pennsylvania Model
(4) Memorial Hospital of Long Beach Model
(5) Memorial Hospital at Easton, Maryland Model
(6) Hamot Medical Center, Erie, Pennsylvania Model
(7) Other Models

## Table 9

## Roles for Clinical Pharmacy Practice

### Ambulatory Care Roles

(1) Ambulatory care clinics
(2) H M O's
(3) Family practice clinics
(4) Outpatient clinics

### Other Institutional Roles

(1) Mental health facilities
(2) Geriatric homes
(3) Home care programs
(4) Extended care facilities
(5) Others

### Drug Information Center Roles

(1) General supportive roles
(2) Poison information and treatment

## Table 10

## Roles for Clinical Pharmacy Practice

### Community Practice Roles

(1) Overall view of various settings
(2) Rural pharmacy
(3) Prescription pharmacy
(4) Urban pharmacy
    a. community pharmacy
    b. chain drugstores

## Table 11

### Number and Types of Pharmacies in the United States, 1968 - 1972

| Year | Independent Community Pharmacy | Four or More Outlets Chain Pharmacies | Hospital Pharmacies | Total |
|---|---|---|---|---|
| 1968 | 43,672 | 7,124 | 4,058 | 54,854 |
| 1969 | 44,642 | 6,460 | 4,617 | 55,719 |
| 1970 | 40,207 | 9,739 | 4,717 | 54,663 |
| 1971 | 39,831 | 10,755 | 4,989 | 55,575 |
| 1972 | 39,998 | 10,604 | 5,174 | 55,776 |

Source: National Association of Boards of Pharmacy, Licensure Statistics and Census. Taken from the National Association of Boards of Pharmacy, Annual Proceedings 1968 - 1972.

## Table 12

### Variations in the Numbers and Retail Drug Volumes of Community and Chain Store Pharmacies 1965-1975

| Year | Number All Stores | Number Chains | Percent Chains | Percent Total Drug Volume |
|---|---|---|---|---|
| 1965 | 56,300 | 12,949 | 23 | 48 |
| 1970 | 53,120 | 15,898 | 30 | 56 |
| 1975 | 46,950 | 18,609 | 40 | 69 |

Reference _Chain Store Age_ page 55, May 1976

# ENVIRONMENT FOR CLINICAL PHARMACY

James T. Doluisio, Ph.D., Dean, College of Pharmacy, University of Texas at Austin

I have been invited to discuss the environment for clinical pharmacy. I do this with some hesitation because I firmly believe what is the best approach for one University is probably best only for that University and cannot be translated easily to any other University. There are many interacting factors that must be considered when a clinically oriented curriculum is developed and these will vary from university to university, and indeed from country to country.

A curriculum must serve students, faculty, the profession, and perhaps most important of all - it must serve society. Our curriculum must change as the needs of society change. In the past generation our profession has changed from an art to a science and superimposed on this scientific base is a socioeconomic component that is of utmost importance. In addition, our profession has changed in the nature of our pharmaceutical services, in the number of people we must serve, and in the extent to which these people are using our services. To a great degree these changes in our profession were the result of changes in our educational programs and were influenced by the changing needs of the public for pharmaceutical services.

After World War II, the pharmaceutical sciences began to have a significant effect on pharmaceutical education. This effect was badly needed and served to stabilize our educational system.

Largely through the influence of the pharmaceutical sciences, our colleges grew in stature on university campuses. However, in my opinion, professional goals often were not understood by the pharmaceutical scientists and pharmacy began to be divided. This division was caused more by our colleges of pharmacy than perhaps by any other group. The two basic supports for pharmacy are, and will be, the Science of Pharmacy and the Profession of Pharmacy. Unfortunately, in recent years the education for the Science of Pharmacy has so dominated the education for the Profession of Pharmacy as to create some very serious problems.

It should be emphasized that it would be wrong for us to over-react and attempt to sacrifice the "science cf pharmacy" for the "profession of pharmacy." This is a short-sighted solution that would lead to other problems in the future.

Professional growth can be and has been limited by educational patterns. It is the responsibility of our colleges to provide our students with an education relevant to today's practice and yet broad enough to allow them to supplement this education as duties change -- and indeed change will come. Look at the change in technology in our life times: in communications (television), in transportation (jets, automobiles, men landing on the moon), in drugs, and in dosage forms. The mistake is often made in thinking that we have reached a plateau and that all change is over for awhile. This is wrong, and, as educators, we would be short-changing our profession if we accepted this assumption.

The students in our classes today will still be practicing pharmacy in 2016. What foundation do we give them so that they can adapt to change or even cause change? This is a difficult question. We are not certain what pharmacy will be in 1986 let alone 2016. However, we are certain that our graduates will not be practicing 1976 pharmacy in 1986. Change is inevitable -- but we can only make intelligent guesses at what these changes will be. Who should make these judgments? It is the College's responsibility to design our curriculum -- but we can no longer do this in a vacuum. We must have faculty leadership -- but it is important that we add to our faculty individuals whose primary concern is in education for professional practice.

## Some Points of General Consensus in the United States

I believe that we have reached some general consensus among U.S. pharmacy colleges on a number of important matters.

1. There is a symbiotic relationship between pharmacy education and pharmacy practice. They are interdependent. It would be very difficult to achieve excellence in one area without having high quality in the other. Thus it is in the best interests of our college programs to increase the quality and importance of pharmacy practice.

2. The pharmaceutical sciences have made very significant advances since World War II. We can take great pride in this development. We have earned full credentials in the scientific community.

3. The practicing pharmacist has not applied to a reasonable extent his excellent background in the pharmaceutical sciences. In the States we have provided good fundamental medicinal chemistry, pharmaceutics, pharmacology, etc. for 25 years - but this education was not transferred into practice. Something was missing.

4. Pharmacy colleges have not done significant research in the area of professional practice development (i.e. the clinical pharmaceutical sciences). Generally, when we had excess funds we invested them in scientific areas. We did not invest it in a way that would directly improve the practice of pharmacy for the baccalaureate person.

5. Clinical Scientists are needed in pharmacy education as they are in the other health professions to advance professional practice and to educate students to best use their academic background. Clinical scientists are also needed to communicate to the basic scientist the needs of the profession and to aid the profession in applying the basic sciences.

6. There is a great deal of overuse and misuse of drugs in society. This improper usage could be partially eliminated and controlled if pharmacists exercised broader professional responsibility.

7. Pharmacy education should move closer to medical education and other health professions education. If pharmacy students are educated in an interdisciplinary setting they will better interact with the other health professionals when they graduate.

The above summary of general consensus dictated alteration of the traditional pattern of pharmacy education. Three main changes have occurred.

1. Practitioner-faculty (clinical scientists) were added to colleges of pharmacy.

2. Voluntary clinical faculty were also added. These faculty are full-time practitioners who serve as role models and instructors in our clinical courses.

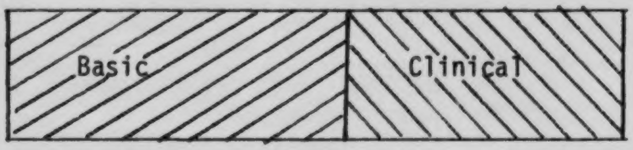
3. We have moved part of our education off campus to real life patient care areas; hospitals, community pharmacies and clinic pharmacies. These off campus sites are the primary locations of our practitioner - faculty and voluntary faculty.

The growth in clinical teaching personnel in American colleges of pharmacy has been dramatic. In 1966 it has been estimated that there were only 31 clinical faculty. However, in only six years this number grew to 714 and I would estimate that we have surpassed 1,000 this year.

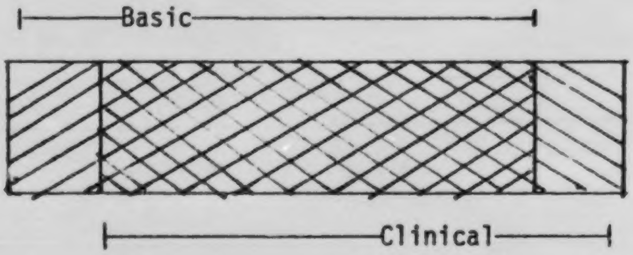
## Curriculum Design

There are basically two types of curricula used for pharmacy education in the United States.

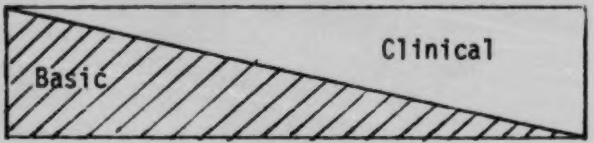
1. The "Block" Curriculum.



In this curriculum all the basic pharmaceutical science courses precede the clinical courses. In some cases there is some overlap of material, e.g.,

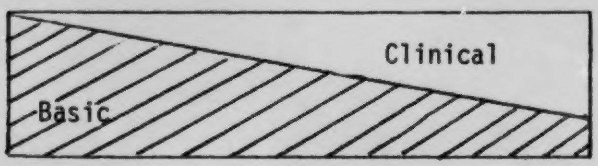


2. The "Diagonal" Curriculum



In this curriculum the student is always taking both "basic" and "clinical" courses but in the beginning of the program the emphasis is on "basic" course and in the senior year the emphasis is on "clinical" courses.

At the University of Texas we use the "diagonal" approach. We believe that it is a logical transition for the students and this approach eliminates the student criticism: "When are we going to get to some 'pharmacy' courses?" Of course, in the diagonal curriculum it is not necessary to have a 50-50 division between basic and clinical courses. I would judge that ours is about 60-40. That is,



## Clinical Pharmacy Courses

The clinical program and the basic science program are equally important and if excellence is sought in each program these programs are also equally demanding in the quality of faculty they require. Clinical faculty should be "academically" equal to our scientific faculty in every way. Of course, the types of teaching and research are quite different.

The clinical pharmacy program has added a new dimension to our ability to educate students. A student's understanding of a subject may be classified into three levels.

1. Recognition and Recall
   This is the most basic level of student understanding. We can use some fancy terms but basically this level requires student memorization.

2. Synthesis and Analysis
   This is a higher level and requires that the student be able to understand and correlate the facts or theories learned.

3. Utilization
   This is the highest level of student understanding - to be able to put his knowledge into action when it is required.

Generally, in undergraduate education, basic courses only develop the first and second levels of understanding. What has been lacking in the past is a clinical segment in the curriculum that develops the highest level of understanding - utilization of knowledge in live practice settings.

## The Teaching Hospital

The environment for clinical pharmacy education for the patient care area and obviously one area that is extremely important for clinical education is the teaching hospital. Here we have the greatest concentration of drug related patient situations and we have the added advantage for education that there is a coordinated effort of patient care that involves all health professionals, i.e., physicians, nurses, allied health personnel, as well as the pharmacist.

The teaching hospital with its dedication to teaching and research is often the ideal environment for clinical pharmacy education. In this setting there is generally an awareness that current methods of patient care must improve and if a pharmacist truly wishes to be involved in judgmental decisions regarding drug therapy, our contributions are welcome. Another advantage is that health professionals educated together are more likely to cooperate better after graduation and a more coordinated interdisciplinary approach to patient care will result.

Thus, there is almost no college of pharmacy in the United States that does not use a teaching hospital for its basic clinical education. In these teaching hospitals, students learn about drug related problems. They learn the value of rational drug therapy and the consequences of poor drug therapy. They learn effective communication with patients and with other health professionals.

The out-patient clinics are an area that has been particularly valuable in clinical education. Here a clinical faculty member informally discusses the importance of drug compliance to a family in a pediatric clinic. The teaching hospital which serves as a teaching lab for a clinical faculty should demonstrate to pharmacy students credible role models. In other words, the student should be able to observe the clinical pharmacy faculty member participating in meaningful pharmacy services. If the faculty member's input to the basic services of the teaching hospital is minimal or artificial, the student will likely classify clinical education as unrealistic and not applicable to his future practice. The clinical faculty member must be a role model, one that the student can pattern his future practice after.

Because of this it is important to have creditable role models for teaching in patient services, such as medicine, pediatrics, surgery, and so on. But it is also important to have equally creditable role models for teaching in outpatient services (e.g., ambulatory care) and in community pharmacy. It is in these latter areas that the majority of our students will practice and we must demonstrate to them that what they learn in the teaching hospital also applies to ambulatory care and to community practice. My own opinion is that it is important to have approximately equal time in the curriculum for clinical education by pharmacists in the teaching hospital and in community practice.

It is clear that as we seek more responsibility for pharmacists in drug therapy we must also provide backup systems for the practitioner. Many colleges of pharmacy have developed drug information services that serve as a teaching laboratory for pharmacy students but also serve the informational needs of practicing health professionals in the region. These drug information centers have become an important component of our educational and service efforts.

Another backup system that is emerging to improve our drug knowledge base is the clinical pharmacokinetics laboratory. This laboratory is designed to monitor drug tissue levels in patients. Again, colleges of pharmacy utilize these laboratories as both a teaching resource and a valuable service to practitioners. These clinical pharmacy scientists provide important information on the adequacy dosage regimens.

Clinical pharmacy services are best built around a strong drug distribution service and indeed the clinical and distribution functions of the pharmacist compliment each other.

Newer roles are often easily superimposed on traditional roles. For example, a pharmacist checking a patient medication profile for drug interactions, etc., prior to the distribution of the drug.

The purpose of clinical pharmacy education is to mobilize the pharmacists knowledge to improve drug therapy. A patient is concerned about the drugs he takes and the pharmacist should aid him whenever possible so that drug therapy is optimized. I believe pharmacists have not been comfortable in discussing drug therapy with patients. This type of communication should be stressed during clinical education.

Patient communication is important for both prescription medication and for non-prescription medication. At this point let me state that I am afraid that I have committed the error that almost everyone makes who speaks on this topic. I have attempted to emphasize the importance of credible role models for teaching pharmacy students and that the environment for clinical education in the teaching hospital and in the community pharmacy are equally important. I wish to stress that in many programs, divisions of student time between the hospitals and the community pharmacies are approximately equal.

In the remaining portion of my talk, I would like to indicate how different schools have approached similar objectives for clinical education. Basically there are three types of colleges of pharmacy in the United States.

1. College of pharmacy at an academic health science center, e.g., University of California, University of Kentucky, University of Minnesota. (Physically and administratively in an academic health science center.) Here is a slight trend in the United States for schools of pharmacy to relocate to academic health science centers.

2. University based pharmacy schools with academic health science centers at a different location, e.g., University of Georgia, Purdue University, University of Texas.

3. University based colleges of pharmacy without extensive local facilities, e.g., Washington State University, Southwestern Oklahoma State University.

Each of these three types of schools has similar objectives in clinical pharmacy education and all utilize both teaching hospitals and community pharmacies in their educational programs. It is interesting to note that even schools such as Kentucky and California that reside within academic health centers utilize distant off/campus teaching hospitals and community pharmacies in their clinical programs.

When I started thinking about this talk, I contacted friends at other schools for their thoughts on the topic. I received a very thoughtful and interesting reply from Paul Parker, Professor of Pharmacy and Director of the Pharmaceutical Services at the University Hospital of the University of Kentucky. I would like to share some of his thoughts with you.

"There are some broad benefits associated with having the College of Pharmacy in a health science center that perhaps many people may not have considered. I believe one should consider the point that as one of the five health science colleges, pharmacy becomes equally involved in overall health science center planning, programming, and policy making. As you know, the Dean participates weekly in an administrative meeting with the Vice President and key members of his staff which involves all of the deans and the administrator of the hospital. In the last year or so, the College of Pharmacy has been significantly involved in planning for a new health science learning center; it has been involved in planning for a health science center for research in aging; it has been involved in planning for a new ambulatory care center; and significantly involved in tobacco and health research on a medical center-wide scale."

"The College of Pharmacy is considered to be a leader among the colleges here in area health education, and there is little doubt that the college here is involved significantly on a medical center-wide basis."

"With respect to the more educationally related benefit, it is my personal opinion that the environment for teaching in a health science center is more patient-centered and educationally-oriented. In the past, this feature has sometimes been considered both an advantage and a disadvantage. Sometimes, health science centers have tended to become too specialized in their orientation and ethereal in their philosophy with an inadequate appreciation for the application of health care to the majority of people. I agree that this is true and that all of the schools in the health science centers should expand their focus to include the actual provision of health care on a regional or state-wide basis. This is the main reason that I have become so enthusiastic in recent years about the value of area health education."

"If you return to Kentucky today, I think you would be surprised at the degree to which we now utilize our faculties in interdisciplinary teaching. Even so, I think we have only scratched the surface in this respect and that interdisciplinary teaching will increase rather dramatically as the various health science disciplines develop mutual confidence and working relationships. I also believe we are now beginning to see the value of interactions of students in the various disciplines through the development of mutual confidence and appreciation for one another. This happens to some degree with the Bachelor of Science students but unusually so with the Pharm.D. students."

I believe these are some special strengths of this type of program. However, it is interesting that the other two types of programs can match many of these advantages with proper planning and dedication.

The College of Pharmacy at the University of Georgia is in a small town and 100 miles from the medical school. However, excellent cooperative programs are developing.

Purdue has been a leader in off campus clinical education. They cooperate with an academic health science center some 50 miles away, various teaching hospitals, community hospitals and a very well controlled community pharmacy network throughout the state.

The University of Texas has a similar situation. The University of Texas System has twelve units, eight academic units and four medical units, at various sites within the state. UT Austin is the major research university of the System and it is the site of the pharmacy college. However, the pharmacy college has cooperative programs with the four medical units and there is very close cooperation between the College and the UT Medical School in San Antonio which is approximately 70 miles from Austin.

The University of Texas Pharmacy program is constructed to provide all the pharmaceutical sciences at UT Austin. Approximately 28 of our 36 faculty are located in Austin - 24 faculty are directly involved in the pharmaceutical sciences and 4 faculty provide off campus clinical pharmacy education/research in the hospitals, clinics and community pharmacies of Austin. Eight of our pharmacy faculty are located at the medical school and university hospital in San Antonio to provide indepth clinical pharmacy programs. Additionally, there are 18 teaching assistants in Austin and 18 teaching assistants in San Antonio.

The first two years of the three year pharmacy baccalaureate program are provided in Austin. Approximately 66% of senior students complete their final year in San Antonio. The M.S. and Ph.D. programs are conducted in Austin and the advanced professional Doctor of Pharmacy (Pharm.D.) degree program is conducted in San Antonio. Hence, we have concentrated our pharmaceutical sciences in Austin and our clinical sciences in San Antonio, but faculty on one campus frequently lecture on the other campus.

Washington State University College of Pharmacy is an example of a school of pharmacy that does not have a university related medical school but has developed an outstanding off/campus clinical program that is required of all senior students.

Some comments from Dean White of Washington State University emphasize the importance of the clinical environment in their school's program.

"The course provides clinical experience in the delivery of health care and the role of the pharmacist in patient care. Most of the students are located in cooperating community hospitals in Spokane where there are three full-time clinical pharmacy faculty as well as part-time faculty in the cooperating hospitals. In addition to four community hospitals in Spokane, there is an affiliation with the Veterans Administration Hosiptal there. We also have affiliation with two hospitals in Seattle. In addition, we have very important relationships with two family practice residency programs and clinics in which our students obtain training along with resident physicians. The clinical clerkship provides eight weeks of experience for the students during which time they are involved exclusively with the clerkship program. That full-time exposure provides opportunity for them to round with physicians in various rotations as well as to learn under the guidance of pharmacy faculty. Interdisciplinary relationships with other health professionals in the hospital is stressed."

"A second component of the off-campus experience available to our students is in a professional practice course that provides an externship in practical professional experience in a variety of pharmacies. Pharmacies are selected for the opportunity they afford a student in gaining experience in patient-pharmacist relationships in an ambulatory setting."

Southwestern Oklahoma State University College of Pharmacy is another example of a school of pharmacy without a university related health science center and in a small town with limited clinical facilities. Because of their dedication to the concepts of clinical education, this college in the past six years has developed an extensive clinical education environment for their students utilizing hospitals and community pharmacies throughout the state of Oklahoma. This college is located about 60 miles from a major metropolitan area, Oklahoma City, where there is the greatest concentration of clinical education facilities. But hospitals and community pharmacies, 300 to 350 miles from school are utilized in the college's program. The main base of operation of the off campus program is located in a 650 bed hospital in Oklahoma. The off campus clinical faculty for this college includes 34 community pharmacists and pharmacists in 14 hospitals.

## SUMMARY

In this presentation the clinical aspects of United States pharmacy programs have been emphasized because they have been recently added to the curriculum. However, the pharmaceutical sciences remain as an important part of the curriculum. In fact, in my opinion, it would be wrong to add a clinical component to a poor curriculum in the sciences. It is the pharmaceutical sciences that have given stature and quality to pharmacy programs - but it is the clinical sciences that must attain better application of basic sciences to patient care.

Recently, the American Association of Colleges of Pharmacy commissioned a report on pharmacy entitled "Pharmacists for the Future." I hope you all study this document because it contains important messages for each of us. One comment made by the Study Commission was particularly disturbing to me.

> "To some observers, including the members of the Study Commission, the greatest concern regarding the nature of pharmacy arises from the unique circumstances which prevail in the pharmaceutical area. The unique circumstances relate to the discontinuities which exist between

> the generation of knowledge about drugs and the application of that knowledge in the clinical use of drugs. In nearly all other parts of the health care system there exists a functional interrelationship among the components involved in the education of health professionals, the delivery of health services to patients, and the search for new knowledge. It involves a corps of basic and clinical scientists seeking new knowledge and its application both to the delivery of health services to patients and to the education of health professionals."

It is obvious that pharmacy has not had this "unified" approach. However, it is not too late to start. We have started in our United States colleges of pharmacy - and we believe that what we have started is extremely important to the future of our profession and to the nature and quality of our services to society.

# CLINICAL CONFERENCE SITE VISITS

Robert Weibert, Pharm.D., Assistant Professor, College of Pharmacy, University of Minnesota

The University of Minnesota College of Pharmacy provided an opportunity for the Congress participants to visit clinical pharmacy practice sites with a faculty member. The objective of these visits was to permit the participants to observe the actual settings where clinical pharmacy is practiced and taught. There was an opportunity for participants to discuss these programs with faculty members, physicians, nurses and other health professionals. Small groups of participants visited each of the following sites:

Anoka State Hospital

- Dr. John Fordice

Hennepin County Medical Center

- Dr. Edward Krenzelok
- Dr. Anthony Manoguerra
- Dr. Robert Weibert

Long Term Care: Nursing Home

- Dr. James Marttila

St. Paul Ramsey Hospital

- Dr. Donald Uden
- Dr. Darwin Zaske

Veterans Administration Hospital

- Mr. Frank Gorgonzola
- Dr. Dennis Griffin

University of Minnesota Hospitals

- Mr. James Clinite
- Dr. Joseph Cornell
- Dr. Albert Edwards
- Mr. Charles King
- Dr. Sharon Lundin
- Mr. Andrew Roberts
- Mr. Roger Schroeder

The site visits were well received and provided an excellent opportunity for faculty and participants to become better acquainted as well as exchange ideas. As expected, one highlight of many of the visits was the tour of the hospital pharmacies.

A special word of congratulations goes to all of our foreign visitors whose remarkable mastery of the English language and general enthusiasm made the site visits a success.

# HOW OTHERS VIEW CLINICAL PHARMACY

Presiding:

Robert S. Tonks, Ph.D.
Dean, College of Pharmacy
Dalhousie University

# A VIEW OF CLINICAL PHARMACY FROM CANADA

Robert S. Tonks, Ph.D., Dean, College of Pharmacy, Dalhousie University

First let me say that we count ourselves fortunate in being able to study at close quarters the various clinical pharmacy programmes in the United States.

Our particular philosophy is that in addition to providing the correct medication, in the correct dose and dosage form, with the correct instructions, to the right patient, pharmacy has a responsibility to ensure that rational drugs exert their optimum therapeutic effect for the prescribed period of time without harming the patient.

We believe it is necessary to provide in-service education on drugs, dosage forms and their utilisation to medical internists, residents and nurses. To provide drug therapy surveillance on patients, patient history taking, medication counselling and education for patients as well as discharge counselling and drug-therapy follow-up for surveillance and compliance at outpatients or ambulatory care centers or the community pharmacy.

We are attempting to produce patient-oriented baccalaureate degree programmes on a strong pharmaceutical science base. Over the last six years considerable innovation has taken place in the baccalaureate programme with the introduction of enriched biopharmaceutics, drug information training, the teaching of pathophysiology of disease, therapeutics and iatrogenic disease (in addition to pharmacology) as well as the behavioral sciences and communication skills, etc. The practicum includes therapeutic rounding, etc.

We see the Pharm.D. graduate in a leadership role providing clinical pharmacy service, whilst encouraging the baccalaureate degree pharmacist to assist in the provision of this service as well. The Pharm.D. will often provide the clinical pharmacy education on the baccalaureate programme.

We do not see the Pharm.D. degree replacing the Bachelor of Science in Pharmacy degree, as the only pharmacy degree, in the foreseeable future.

We encourage our Pharm.D. faculty to become involved in research or investigative work. We, like our American colleagues, hope that substantial data will be available in the not too distant future in the area of clinical pharmacy practice including the evaluation of the cost effectiveness of the clinical pharmacist and the benefit he brings to the patient and members of the health team.

Such data would be of considerable value to countries and colleges wishing to initiate clinical pharmacy programmes - particularly where government pays the health bill.

Canada has 44 Pharmacy Residency Programmes of 50 weeks duration with a good clinical practicum. All are affiliated with the Colleges or Faculties of Pharmacy. At the present time we have no Pharm.D. programmes in Canada. Three

Pharm.D. programmes will be started in the near future, one of them being at Dalhousie University.

The employment of the Pharm.D. graduate at Dalhousie University:

1. Faculty positions have a service component built into the appointment.
2. Prior to the appointment considerable advance discussions take place with physicians/surgeons
   nursing staff
   pharmacists
   hospital administration
   university administration

   a. on the need for clinical pharmacy services and education.
   b. to fix the job description, duties and responsibilities.
   c. to ensure that the Pharm.D. graduate becomes a member of staff of the hospital's department of pharmacy as well as the faculty position in the college.
   d. the ward, unit or department is defined and number of beds clearly agreed upon before the appointment begins. Choose the clinical unit with the best chances of success.
   e. we build in a review procedure for the two institutions and the clinical pharmacist. The position is reviewed every six months for the first year, then annually.
   f. we continue the advance publicity of this appointment to the hospital personnel.
   g. when all the conditions for appointment have been completed we choose a candidate of high academic standing, with the right personality for the job in question.
   h. the college needs to provide support for the clinical pharmacist with a good drug information resource facility and where possible a lab, etc.
   i. the college pays the total salary of the clinical pharmacist and recovers the service portion of the salary from the hospital or institution.

These clinical pharmacists in addition to their service function:

1. teach our pharmacy undergraduates
2. teach our pharmacy residents
3. help us to establish a team approach in our educational role model
4. establish the clinical faculty in readiness to teach our Pharm.D. students when they come-on-stream
5. are encouraged to do research.

# THE PHYSICIAN

Robert P. Heaney, M.D., Vice-President, Health Sciences, Creighton University.

## I. Background

Creighton has had eight years experience with Pharmacy students working side-by-side with medical students in several ward settings. Early on this produced two perceptions which have subsequently been verified, year-by-year, with new groups of students: (1) the Pharmacy students found that they knew things the Medical students didn't, and could make a significant contribution, and (2) the medical students came to realize how much more about drugs the Pharmacy students knew, and came to respect that knowledge.

Creighton has had somewhat more than two years experience with the assignment of Pharm.D.'s working full-time in a variety of clinical settings, both in the supervision of the senior Pharmacy students assigned to those settings, and also interacting as members of whatever health care team may be working on the clinical unit concerned. To date patients in all of these settings have been of the "service" variety, virtually none of them private-pay. The services have been in Pediatrics, Internal Medicine, Family Medicine, and Psychiatry, have been both in-patient and out-patient, as well as in nursing homes. We have had no experience with clinical pharmacists on Surgery wards or in intensive care settings.

## II. Physician Survey

I have personally interviewed a cross-section of the physicians responsible for, or staffing, the services on which the clinical pharmacists have been working. As might be expected, the responses varied widely, but the range was heavily shifted toward the positive side. There were no negative reactions whatsoever, and the coolest response was a single one of simple neutrality. In all other cases the physicians felt that the clinical pharmacists were helpful. In many cases the response was "very helpful."

None of the physicians felt threatened by the addition of the clinical pharmacist to the ward team, and none of them indicated any difficulty in accepting suggestions or input from the clinical pharmacists. Most went on to say that they also experienced no difficulty in rejecting suggestions with which they did not agree, and none seemed to have any question about who was "calling the shots."

There was a full spectrum of response with respect to whether clinical pharmacy represented "icing on the cake." This ranged from such reactions as "helpful, nice to have around, but not necessary;" to "we need them!"

One of the senior internists with whom the clinical pharmacists worked, commented that they were specifically useful in matters of drug interactions, an area which, he went on to say, "physicians can't keep up."

Another senior clinician who found them "helpful, but to a limited degree" commented that they were of special value in terms of patient instruction on medications, and also visualized that they could be of great benefit in small private hospitals. He, working in a large institutional setting, indicated that they might serve a very useful role in the conduct of audits relating to drug utilization, with particular emphasis on expense and benefit, a role which he felt the regular hospital pharmacists were not able to play.

He finally went on to say that he thought clinical pharmacists might be of "tremendous" use on the Surgery wards, and that perhaps Internal Medicine was the "wrong place", in view of the classical role of the internist with respect to drug therapy.

Psychiatric staff members gave uniformly positive responses, stating that the clinical pharmacist provided the medical students with more "good factual information" than did anybody else, and went on to say that now, having experienced clinical pharmacists, they would want to have one on the Psychiatric Wards, even if we were to transfer the currently assigned man to some other setting. One psychiatrist commented that he thought that "internists might be a little slow to accept the concept."

A psychiatric resident was even more positive, indicating that drug information was increasing geometrically and that the physician simply could not keep up. She felt that the clinical pharmacists, in her brief experience on both Internal Medicine and Psychiatric services, played an essential role. She stated emphatically that she would not want to be without their help.

An Internal Medicine resident, by contrast, felt that they were definitely "icing on the cake." Nevertheless he was emphatic to the effect that he found the clinical pharmacist extremely helpful, particularly in terms of rapid retrieval of information, indicated that they certainly knew their pharmacology much better than did physicians. Another internist, in this same vein, in what he thought was praise for a clinical pharmacist's contribution, characterized him as "a walking PDR."

A family practitioner found that clinical pharmacists helped tremendously with patient care, particularly in the nursing home setting, and noted that problems of drug compliance were much reduced as a result of having the clinical pharmacist as a member of the team. He definitely felt that their role was more than one of "icing." Another, while doubting better compliance, said however that he was now better aware of the patients who were not compliant than he had been before.

## III. Comment

Special Status of the Internist. Because his stock in trade is drug therapy, the internist, of all specialities, is probably least likely to depend upon someone else for drug advice. Our group of internists, nevertheless, universally found the clinical pharmacist useful and helpful, even if not in their view essential. The perspective of the psychiatrist with respect to the acceptance by the internist is interesting, as is the perspective of the internist with respect to the importance of clinical pharmacists in a surgical setting (in which internists generally hold that surgeons use drugs recklessly and inappropriately).

One senior internist told me that, since surgeons are reluctant to accept advice from internists, he wasn't at all certain that they would take it from clinical pharmacists any more readily.

The Unique Perspective of the Physician. As a class, physicians generally fail to perceive any health care function if it cannot be at least potentially enclosed within the field of medicine. Hence they tend to see all health professionals as somehow "physician extenders", in the broad sense of that term. (This perception has been particularly vexing in terms of the unique role of Nursing, and the conflicts which have arisen in the intersection between these two professional groups.)

Hence, because of inevitable medical chauvinism, physician perception is not an adequate context in which to define the role of clinical pharmacy, though it definitely must be considered in planning for both the utilization and education of the clinical pharmacists.

Impact of Clinical Pharmacy in an Educational Setting. The senior staff professionals with whom I consulted had all learned their roles before clinical pharmacy was "invented." Whereas they appear to have adapted well, it is still not the same thing as learning their role in a setting in which other health professionals already have a specific job to perform. The residents tend to adopt the attitudes to their mentors, and so change may not be as rapid as might be desired; nevertheless students are now developing in a context in which they learn not only the content of their field, but also the specific functional competencies of other health professionals, and it seems inescapable that in doing this they learn the necessary functional dependencies which will condition future attitudes.

## IV. Synthesis

With respect to the principal questions which were posed, it seems that the physician still sees himself securely as the "leader" of the health care group, and that he is in no way threatened by the emergence and existence of clinical pharmacists as members of his team, nor in receiving and reacting to specific input from clinical pharmacists with respect to drug therapy.

We at Creighton have deliberately assumed a non-aggressive, positively helpful posture for our clinical pharmacy services, and it seems evident that our clinical pharmacists have succeeded in creating a positive image for themselves and for their professional role. We now find ourselves dealing with requests to provide more ward clinical pharmacy services than we have the professional manpower (or budget) to cover. We believe that, for us, this has been the right strategy.

It is probable, however, that the present physician reactions represent principally transitory phenomena. Hopefully this country is moving toward a rational system of health care in which needs are first defined, and then appropriate resources are identified and mobilized to meet those needs. When a benefit package and the available resources are both fixed, it seems inescapable that the system will quickly realize the benefit which can be achieved by the greater deployment and utilization of such professionals as the clinical pharmacist.

Extended care settings provide an obvious example of these constraints, and thus it is not surprising that Clinical Pharmacy has early demonstrated its usefulness and cost effectiveness in such settings. We at Creighton use them extensively for our Pharmacy educational programs.

# HOW THE NURSE VIEWS CLINICAL PHARMACY

Rachel Z. Booth, RN, MS, Director, Ambulatory Nursing, School of Nursing, University of Maryland

I am pleased to participate in your meeting and to share some of the considerations and reflections of members of my profession. I have been asked to spend a few minutes presenting the nurse's view of the clinical pharmacist. At first it appeared as a rather innocuous topic, but after careful consideration it became more and more difficult to deal with. I am sure you will appreciate that there is no such thing as "the nurse's view", just as there is no such thing as "the pharmacist's view". Instead, there is a whole spectrum of viewpoints, emanating from many types and levels of nurses, and from a great variety of circumstances and geographical locations.

Therefore, my plan is to present my personal view which somewhat reflects that of my nurse colleagues in the University setting, and also identify other viewpoints from various nursing groups throughout the United States. I will approach this by considering the most constructive positions of nursing, collectively, and my own exciting and rewarding relationship with Clinical Pharmacy at the University of Maryland.

There are two basic tenets that provide the framework for this presentation and from which I view roles and functions for health care personnel. The first and foremost one is that our reason for being is the patient. Second, the planning of roles and functions emerge from the services needed by the patient and from the worker who can most effectively and efficiently provide these services. Thus, the patient remains the focus for developing educational programs, health service systems, and roles of health workers.

These basic tenets apply equally to all health professions whether it be nursing, pharmacy, medicine, or any other. Most of the disagreements or arguments which arise between health professionals are the result of a failure to keep these tenets in mind. Too often our health professionals expend their time and effort for the sole purpose of protecting - or - expanding their own territorial imperative. These wasteful and destructive arguments are not primarily for the patient's benefit, even though this is often used as an excuse.

Fortunately, there are groups who have used the patient focus as the basis for their planning. These groups have also recognized the need for involvement of other disciplines in the development of new roles, such as the nurse practitioner, and in the enhancement of all roles. Further, their efforts have been directed toward the highly desirable goal of demonstrating that optimal patient care is our highest priority and surmounts the difficulties of role competition and interaction between professionals.

An example of such an approach is illustrated in the recommendations of a thirty-six member nursing group that is representative of all nurses in the fourteen Southern states. From 1972-1975 this group worked on a Nursing Curriculum Project of the Southern Region Educational Board, and had as one of its purposes to plan the future of nursing education and practice and relate these to the health care needs of the population. For those of you who are not familiar with the Southern Region Educational Board, it is a formal organization established to assist the fourteen Southern states of the United States to improve the quality, support, and opportunities in graduate and professional education. One of the recommendations that resulted from the Nursing Curriculum Project was the strong encouragement to establish an integrated interprofessional approach in our education and service systems, stating that "as professions are becoming more interdependent, nursing should contribute to and benefit from other disciplines, and work toward establishing interdisciplinary and interprofessional relationships such as the following":

> a. Curricular structure should be interdisciplinary as well as intradisciplinary. Cooperation and collaboration with other health care disciplines should be sought actively by nurse educators, with joint courses encouraged as appropriate at several levels and with nursing faculty having joint appointments in other departments.
>
> b. Nursing should actively explore advances in communications technology, participate with other disciplines in its use for instruction, and participate in the operation of complex communication systems for the delivery of instruction to remote populations and for achieving closer interinstitutional contacts.
>
> c. To insure nursing input into new knowledge about health programs, more researchers must participate on interdisciplinary research teams studying these problems (SREB, 1974, p. 43)

If you will, consider for a moment the implications of this recommendation for the professions of nursing and pharmacy. This representative nursing group is strongly encouraging interdisciplinary educational programs both within and between institutions, and via communications technology to outreach areas. It is also encouraging interdisciplinary research in health programs. Such an involvement requires mutual cooperation, collaboration, and trust on the part of each profession.

If we can successfully accomplish the interchange of teaching - learning roles between professionals during their educational process, we will within one decade change the role interaction climate in our health practice settings. This has been accomplished at the University of Maryland where the Clinical Pharmacist serves as a teacher for medical students, house staff, undergraduate and graduate nursing students and dental students. In turn, clinical pharmacy students are taught by medical, nursing and dental faculty and all of these students have their clinical education in common health service delivery areas.

It is reasonable to conclude that the pharmacy profession has been involved in such interrelationships for the past several years, otherwise you would not have progressed to the conference which you are holding now. The clinical pharmacist has been successful in penetrating a strong triad of nurse-patient-physician, and has done it very well. Initially, this was difficult for nurses to accept and some writers state that nurses were fearful of the pharmacists "taking over the nurse's role". Frankly, I don't think this fear was relevant; however, a conflict did ensue when pharmacists started assuming the responsibilty for drug administration and monitoring in the hospital. Nurses were opposed to the change, maintaining that drug administration, counseling, teaching, and taking drug histories were solely within the nurse's province. They also believed that administration of medications was more than a task, and that it provided an excellent opportunity to evaluate and provide other services to the patient. Therefore, the nurse felt that she should be the person administering medications. As you are well aware, a study was conducted to determine if nurses did what they purported to do and it was found they did not (Martin, 1970). It is not surprising that nurses would have such a reaction, especially since the pharmacist had previously been known as the "counter-man", "pill-pusher", and "narcotic-keeper". Historically, the major form of contact the pharmacist had with the nurse and patient was when he filled an order or prescription from the basement of a hospital or from a community drugstore.

From a personal view, I was very much opposed to having another health worker join the numerous persons that interacted with the patient. I was adamant concerning the problems that this new worker would cause. As I reflect on the discussions with our School of Pharmacy, it seems that my purpose was to protect the patient, protect him from an additional person who now wanted to move into the clinical area. I could not see any useful purpose the pharmacist could serve except to deliver the medication, yet the patient had a right to expect more. In my reflections, I see that representatives of the School of Pharmacy were very effective politicians, salesmen, or whatever you may call those who convert nonbelievers. They were extremely patient and demonstrated a sincere desire to work with other professions and the patient. They also appeared quite confident that they had a unique contribution to make and it encompassed more than technical tasks. In fact, they moved so rapidly and effectively that I didn't even have a chance to become paranoid. We now have a feeling of relief to know that a knowledgeable individual has the responsibility and will be held accountable for pharmacotherapeutics in our health care delivery and educational systems.

It is difficult to determine the current magnitude of opposition to clinical pharmacy by nurses. It is reasonable to postulate that such beliefs are on the decline and will parallel the rise in influence of clinical pharmacy as to numbers, competence, and distribution. A certain amount of opposition will always be present and will be helpful in that it will cause us to ocassionally pause and re-assess our goals.

In preparing for this presentation, I thought it would be most appropriate to poll representatives of nursing groups in the State of Maryland to determine their views of the clinical pharmacist's role. The results from this poll confirmed that we are advanced much beyond the struggle over who should perform basic level functions. Their views were very much patient-oriented and not nurse-oriented. The clinical pharmacist was viewed as an expert on drugs and served many roles in direct and indirect patient care, research, and education. Thus, the input from these nurses provided me with the concerns the nurses have as the new role evolves and the following functions for the clinical pharmacists.

He must be a major participant in the conduct and performance of audits on the quality of care that is provided. Such audits are conducted to provide immediate feedback to the individuals responsible for that care. This serves two purposes, that of continuing education for the providers and improved care for the patient. The results of the audit may cause an immediate change in the pharmacotherapy and prevent such action in the future, if it was found inappropiate. In order to perform audits, standards for the outcome and process of care have to be established. The clinical pharmacist has an important contribution to make in the establishment of these standards in order to provide the pharmacotherapeutic expertise which is needed. For example, the Chairman of our Ambulatory Audit Committee is a clinical pharmacist and the committee membership is comprised of physicians, nurses, and clinical pharmacists.

While the in-patient (particularly in our extended care facilities) has many pharmacotherapeutic problems, it is the ambulatory, primary health care area which provides an exciting and extensive field for research to improved care. The clinical pharmacist is expected to participate in identifying problems and conducting research to create new knowledge, e.g., designing methodologies for monitoring the effectiveness of pharmacotherapy, determining the nature and cost effectiveness of prescribing patterns, and developing basic data concerning drug interactions.

Another function for the clinical pharmacist is to provide a consultative service to other professionals concerning a plan of therapy for individual patients. This means that he must be involved in developing the patient's care plan both on an in-patient and ambulatory basis. The pharmacist must participate in regular patient conferences with other professions. But in order to be utilized, the pharmacist must be accessible and available in the clinical area. If he is located in the next building or away from the area, even though he can be reached by telephone, don't be suprised if he says he is under utilized.

The need for teaching and counseling patients on the use, mis-use, and abuse of drugs is tremendous. The pharmacist is the ideal professional to provide drug information to patients in the health care agency and in the community. A significant savings in terms of monies, not to mention human happiness and time, could be realized from such an educational program just in the area of over-utilization of drugs, self-medication, and adverse reactions. With the literature showing that adverse drug reactions cause 1 1/2 million individuals to be hospitalized annually, it seems that many of these hospitalizations could be prevented if the individuals had more information about drugs.

Not only does the patient need information on drugs, but the other professionals with whom the pharmacist works need an on-going program for staff development or continuing education. Some of my nursing colleagues have expressed a fear that the clinical pharmacist will become so busy that he will fail to recognize this need.

Direct patient services are a part of the clinical pharmacist's role, but the functions will vary according to the population served. In some instances, the clinical pharmacist may be the primary provider, that is, he will provide the majority of the care and remain the principal contact during a certain phase of the client's health-illness. In general, the pharmacist serves a major consultative and supporting role in obtaining and recording drug and related histories;

performing screening activities; monitoring the client's response to a pharmacotherapeutic plan as well as the cost effectiveness of therapy; and participating in the development and revision of care plans.

Finally, the clinical pharmacist has an important role in the formal interprofessional education programs in undergraduate, graduate, and continuing education. Professionals should work together in planning, teaching and evaluating educational experiences and when feasible, combine efforts, teachers, and students. There are at least two benefits from this approach - decreasing educational cost and preparing the different professions to appreciate and understand each other and the unique contributions that each has to offer.

The preceding beliefs as to the role of the clinical pharmacist did not occur to my nursing friends over-night. Instead, it is the result of a gradual evolution in attitudes, trust, cooperation, and sharing. Considering the large number of important contributions which we have identified, it is not surprising that an equal number of serious questions will arise concerning the preparation, cost and effectiveness of adding a new health professional role to our already complex and often dysfunctional health care system. It is interesting that we now expect new and emerging health professionals to justify their existence through careful research into their productivity and effectiveness in terms of the process and outcome of health care. However, this is probably a desirable trend and is a sign of the increased accountability to be required for all health professions in the future.

In general, the concerns that nurses express about the clinical pharmacist are the same as they have toward any new professional role, including ones within our own profession. A major concern is that communication will be lacking concerning what the pharmacist is doing in the clinical area. It is common to hear nurses say that not enough groundwork is being done before the pharmacist arrives; however, that feeling could reflect a general lack of understanding which dissipates as the two groups work together. Another concern expressed by nurses is that they will lose knowledge of the drugs the patient is getting, and in so doing, the nurse will lose a comprehensive grasp of the patient's care. A major concern that is directed not only at the pharmacist but to other professionals as well, is the cost of health care.

Hopefully, clinical pharmacists will not congregate in University Centers but will move their valuable and much needed services into underserved populations and geographical areas. There are many drug problems in these underserved groups due to self-care and lack of adequate numbers and kinds of providers.

In my experience, all of these concerns are replaced by an overwhelmingly positive response, once the opportunity to work together has been provided. However, it is very important to recognize that acceptance of the concept can occur only as rapidly as competent clinical pharmacists can be produced and placed in service and educational settings. Success will come only with a demonstration of in-depth knowledge, ability to work collaboratively with other professionals, and a feeling of collegiality with other professionals. If an effective working relationship has not been established between the traditional roles of nursing and pharmacy, then it will be more difficult to establish the new role of clinical pharmacy.

Confusion over territoriality is bound to occur. There will always be some overlapping of functions, but duplication of effort and services purely to satisfy professional egos can not be tolerated. Each professional should have a clear understanding of his unique role, the contributions he can make to the patient and other health workers, and the improvements in patient care which occur through interprofessional cooperation. Frequent, open, two-way communications to include patient and teaching conferences facilitate such an understanding.

As you can see, from my own personal experience, I have learned the value of the inclusion of the clinical pharmacist on the health care team. However, I'm no dreamy-eyed idealist. This has occurred only where mature people are willing to discipline themselves to achieve excellence and to demonstrate that their primary concern is for the patient, not professional territoriality.

# How The Pharmacist Views Clinical Pharmacy

William Appel, President, American Pharmaceutical Association, University of Minnesota.

Chairman Tonks, members of the panel, members of the congress, guests, ladies and gentlemen.

It is a distinct pleasure for me to be here with you this morning to share with you some of my thoughts and concerns regarding "the newest development of our professional practice" -- this thing we call Clinical Pharmacy. I would also like to welcome those of you who are visiting our country, and our state. It is a pleasure to welcome you to marvelous Minnesota.

I was most pleased to accept your kind invitation to address this important conference for a number of reasons. First, I believe it is important that practicing pharmacists who make up the vast majority of the profession be heard with regard to their thoughts and concerns on clinical pharmacy. Secondly, as a practitioner who has emphasized clinical functions in his own practice and has expanded his practice greatly by working with recent graduates with extensive clinical training and education, I feel I have more than a casual interest in the subject and can speak from a base of experience which relatively few practitioners may have.

At the outset, I should like to raise an issue which has plagued most practitioners ever since the pharmacy literature began to use the term "clinical pharmacy", "clinical pharmacist", "clinical pharmacy services", and "clinical practice" -- that is the matter of definitions. So that I might be clearly understood for the balance of this presentation, I want to establish some definitions which I shall utilize in answering the questions which have been posed. Questions cannot be adequately answered without first establishing some ground rules of mutual understanding.

## DEFINITION 1 - CLINICAL PHARMACY, CLINICAL PHARMACY PRACTICE

These terms are synonymous with pharmacy and pharmacy practice. Pharmacy and pharmacy practice are, by definition, clinical in nature. That is, pharmacy practice deals with patients. While there are specific functions in pharmacy practice which may not be involved directly with patients, such as drug stability, and formulation, there are other functions of pharmacy practice which are specifically clinical in nature, such as assuring rational drug therapy. There may be varying degrees of performance within pharmacy practice; perhaps some practice is "more clinical" than others, but I submit, and for the purposes of this presentation will maintain, that all pharmacy practice is, by its nature, clinical.

It is true that there is a clinical movement in the two major environments in which pharmacy is practiced - the community and the institution. Greater attention to patient consultation, patient medication profiles, monitoring drug therapy, and better communication with physicians characterize this trend. Further, we see attention to unit dose and self diagnosis and self medication in the community pharmacy as clinical activities particular to these environments. Without detracting from the movement towards more clinical involvement of pharmacists, it is my belief that these are not new roles that pharmacists are performing, but roles which have been neglected by the profession and functions which the profession is only now getting around to recognizing and implementing.

We must be aware, therefore, that services performed under the term "clinical" are usually those services and functions which one should expect from a pharmaceutical service program.

## DEFINITION II - CLINICAL PHARMACIST

This term has caused a great deal of concern among many pharmacists. Some feel that the term is redundant in much the same way that the term "clinical physician" would be redundant. Others feel that they have a level of training and practice more specialized than other pharmacists and use the term to differentiate their training and their practice from the rest of their collegues. There are a group of pharmacists who have extensive training in clinical pharmacology and therapeutics and have demonstrated their value to patient care in both institution and non-institutional settings. These individuals have been referred to as "clinical pharmacists" although a more appropriate descriptive term might be "therapeutic specialists" or "applied pharmacologist".

I believe you can begin to see some of the confusion that has resulted in the profession. Are the services performed by a therapeutic specialist called "clinical pharmacy" services, or are the clinically-oriented services performed by pharmacists called "clinical pharmacy services?"

If using the term "clinical" to describe a variety of functions performed by a variety of pharmacists with a variety of training backgrounds is confusing, then awarding a variety of degrees to practitioners is even more so. Today, we have pharmacists who call themselves "clinical pharmacists" and who possess bachelor of science degrees, doctor of pharmacy degrees, master of science degrees, and some with doctor of philosophy degrees. Many schools of pharmacy have developed clinical pharmacy programs leading to a doctor of pharmacy degree, while other schools award the doctor of pharmacy degree to all graduates and still others award that degree to pharmacists who have taken special courses in manufacturing or other aspects of pharmacy practice. The need for consistency among the profession in terms of degrees awarded for training received is absolutely critical.

Our chairman has provided me with a list of 9 statements or questions to which he has asked me to respond. Based upon my own personal experience, and perhaps personal opinion, I am pleased to respond to those questions and will be glad to respond to your questions at the close of the program.

Question #1 - Please comment on the impact that the development of clinical pharmacy has had on community pharmacy practice as well as on the pharmacists's involvement in extensive nursing home programs and in the clinic.

I have the personal privilege and pleasure of working with several pharmacists possessing extensive clinical training in the course of my own practice and can attest to their significant contribution in long term care nursing facilities, hospitals, physician clinics and other practice settings.

Our profession should be proud of these developments and should continue to pursue the development and expansion of these critically important roles. For all of that, however, these efforts in my judgement have not been directed at the center of the target. The target which represents effective and efficient health care delivery to the total population of this country - a community clinical practice.

We hear much these days about the primary physician being the key to the successful delivery of health care. Who is this primary physician and what does he do? I would suggest that, yes, we have primary physicians in this country. We have about 200 million of them. The primary care providers represented by the mothers, and fathers and families of patients and indeed the patients themselves. I agree with the statement recently made, that health care and maintenance of good health is basically a lay function, with professional services as a supplementary resource. There is no limit to what a properly educated and advised lay person can do regarding self care for himself and his family.

We need role development and expansion of the professional as the family practice pharmacist. While time here today does not permit full development of the role of this professional, suffice to say that the family practice pharmacist is particularly well qualified and available to advise on the use of, and monitor the effect of, over the counter preparations, as well as prescription medication therapy, to detect allergies, adverse and inter-actions and evaluate proper drug utilization.

With auto therapy a major part of the individual's drug therapy program (in illnesses treated with drugs, 30% are treated with prescription drugs and 70% are treated with non-prescription drugs). The family practice pharmacist is the professional nost available, accessible and qualified.

The consequence of improper drug use, when coupled with the consequences of noncompliance, are producing in this country, untold but unnecessary time loss, financial loss, discomfort and suffering. Further, this family practice pharmacist, performing in a coordinated triage relationship with the physician and the nurse, can monitor drug effectiveness, laboratory results and vital signs to measure therapeutic success, determine continuity of treatment, and provide entry into the health care system.

Within parameters established by physicians relating to particular patients, the family practice pharmacist can assume the responsibility for the initiation of drug therapy. In time, I believe, there will be a class of drug products for which the pharmacist will have the responsibility of initiating treatment. We are told that our profession is an information and a knowledge system. This is perhaps true and certainly important. However, in my opinion, it is also short sighted and self defeating, unless we also seek and strive for a judgement role.

Computers store knowledge, machines can print, and the media can disseminate information. It is only when we arrive at judgments based upon our knowledge and information that we will be performing the professional service for which our education prepares us.

Development of such a role will provide the profession with definable standards of practice, as well as a goal for our now scatter gun, non-objective, continuing education efforts.

The recent graduate, with clinical training can, will and does, as I have seen in my own practice, move very well into a service, as well as a teaching role as he integrates into community clinical practice.

The impact of the pharmacist involvement in long term care and physician clinics is significant. While the pharmacist has long provided a consulting service for long-term care facilities, the greatest major development regarding clinical functions has been the pharmacist monthly drug regim review as required by federal regulations governing long-term care facilities.

Where this review has been done diligently and professionally with the object of improving patient care rather than providing "paper compliance" the pharmacist has definitely demonstrated the important contribution he can make. In doing so, the use of his service has greatly expanded: Extensive inservice training, the conducting and interruption of drug utilization review studies, recommending and advising on drug distribution policies and procedures, constructive input to committee functions, i.e. infection control and safety committees, and participation as a regular member of the patient care conference team.

His impact has been significant by his identification of areas of potential: (1) to reduce the incidents of medication error, (2) to reduce clinically significant adverse drug reactions and interactions and (3) to reduce the number of inappropriate or potentially unnecessary drugs. We have also seen this professional service expand into physician clinic setting with significant impact and improved utilization of medications.

Question #2 - Could you share your experiences in the development of role models in clinical pharmacy. In particular, could you define what part the community pharmacist can play in helping to evolve role models for the health professionals in the health care of the patient. How does the pharmacist prepare himself for participation in that role model?

The term "role models" has been used frequently by pharmacy educators and just as frequently with varying meanings. My perception of a role model in pharmaceutical education is a practicing pharmacist whose practice is at such a level that students will want to emulate him in their own practice in years to come. Role models may be preception in pharmacy training programs, clinical faculty members, or pharmacists visibly demonstrating the viability of innovative forms of practice.

Those pharmacists associated with me who are delivering clinically oriented services to patients in long-term care facilities definitely are role models. To the extent that we can improve the level of service we provide and expand the functions we offer, we will develop further our role model functions.

Our particular experience in the development of a role model of clinical pharmacy in the long term care facility setting began with the monthly drug regiment reviews. Upon completion of the first review (which had been initially

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accepted by administration and medical directors because it "was required"), the nature of our comments was such that they produced considerable reaction. As we commented on potential adverse reactions and inter-actions and particularly as we commented on proper drug utilization and rationale of drug therapy, it became apparent that ours was not a service of "paper compliance" - - it was instead, our declaration that we could make a contribution as a member of the medical team, and so it has developed. The answer for improved patient care lies with this medical team concept.

However, we must demonstrate what can be done, not just talk about what can be done. The graduate with clinical experience is obviously well qualified for this role by virtue of his formal education program. The bachelor of science graduate is, I feel, also well qualified and capable of functioning in this role, with additional study and educational experience in the disease states of the geriatric patient, and the use and effect of specific medications by this age group. This individual must, of course, avail himself of a great deal of information, update his knowledge on medications, medication utilization, drug action, drug inter-action and must do this in an orderly concentrated course of study. Key to the functioning successfully in this capacity, is the development of a resource library of both basic information, as well as current professional, medical and pharmacy journals and articles relating to new studies and new information as it develops. Maintenance of competence is extremely important.

The concept of continuing education can be particularly appropriate in maintaining that competence.

With regard to defining what part community pharmacists can play in evolving role models, it seems to me that these role models already exist. It is the responsibility of our schools of pharmacy and the profession to identify those community pharmacists who can serve as role models and provide the necessary incentives for them to do so. Community pharmacy practice must be experienced in the environment in which it occurs -- that is, the community pharmacy. Unlike the medical students who receive the primary bulk of their training in hospitals, much of the training necessary for pharmacy practice must take place in the environment in which care is delivered. That may be the hospital, the long-term care facility, the organized group practice of medicine, or the community pharmacy.

There are many pharmacists practicing near schools of pharmacy who can serve as role models, if they are motivated and compensated for such activity. Obviously, these practitioners must meet minimum criteria established by the school in cooperation with the state or local pharmaceutical association in order to serve as preceptors or role models.

There seems to be a perception among many individuals that pharmacists who serve as role models must be involved in only the most sophisticated pharmacy roles. This is contrary to sound educational principles. The thing that pharmaceutical education should be emphasizing is the preparation of pharmacy students to practice in today's environment and yet have the capacity to function in tomorrow's health care system as well. Unfortunately, many schools have sought to emphasize the future aspects of pharmacy practice, neglecting completely current modes and methods of practice. This is grossly unfair to students and to the profession.

It may be a difficult job relating sophisticated aspects of clinical practice to the current environments of care, but it is a job which must be done if we are to effectively prepare students to practice pharmacy.

Question #3 - Would you comment, from a pharmacist's point of view, what being involved in clinical pharmacy practice has meant to the actual pharmacist himself? What has such involvement done to his relationship with the other health professionals?

I should like to rephrase that question for the point of view of clarity along the following lines, "Please comment from your own point of view what your emphasis on clinical functions in your own practice has meant to you and to those pharmacists who serve with you? How has such emphasis effected the relationship with other health professionals?"

Based upon our own experience in long term care facilities over the last year or two we find we have now been accepted as an integral part of the medical health care team. While there have been considerable growing pains and a number of very rough spots in the road, our relationship with physicians has now become more that of a partner in improving patient care. Our comments and opinions are now accepted objectively and professionally and are given consideration. Our opinions and recommendations are sought in the evaluation of drug utilization. The nursing profession has reacted very positively in seeking our advice. In this setting our practice is drug-patient related, drug-disease related, rather than drug product related and as such does provide a different facet of professional practice. The pharmacist in this setting has been able to present that facet of our profession and in doing so has produced measurable improvement in patient care.

Question #4 - How does one encourage other pharmacists in the community and in hospital to make their professional activities more patient-oriented?

It is not so much a matter of encouraging other pharmacists to make their professional activities more patient oriented, though some may be reluctant. It is more a matter of demonstrating by role models the fact that opportunities exist for this type of professional practice, and that once the pharmacist sees the opportunity and the potential for expanding his professional experience, will on his own initiative begin to generate greater interest and involvement.

Questions #5 and #8 - How does the public view the introduction of a clinical pharmacy service in their local pharmacy? Has clinical pharmacy practice in the community benefited the patient?

For clarity I should like to rephrase these questions as follows:

How does the public view our emphasizing clinical functions in our pharmacy?

Has the emphasis of clinical functions in the community environment benefited the patient?

There is no question but what the community, or at least individual patients within the community, have benefitted from the clinical aspects of the pharmacist's professional practice.

Individual patients have benefited by virtue of the pharmacist monitoring for compliance with physicians orders; by monitoring for duplication of medication orders; and by monitoring for potential drug interactions and adverse reactions but unfortunately the public at large is very much unaware of the professional services provided by the pharmacist, as demonstrated by the newspaper articles on prescription price surveys and, more recently, Justice Berger's opinion in the Supreme Court decision on the Virginia case. The effect of the pharmacist's clinical service has been the improvement of patient care. It is all too apparent that not only is the public unaware of the professional services available and the significance of those services, but that we as a profession have done something less than a good job of informing them. The profession faces a great challenge to remedy this situation. For too long we have been product oriented rather than professional service oriented. We must each within our own sphere of practice demonstrate the significance of our service in order that the public will become aware of the professional service we are providing and the significance of that service.

A major job which faces pharmacists in all environments of practice who are emphasizing their clinical functions and roles is to demonstrate to administrators, other health professions and the public, that these functions are cost effective in delivering health care. We know, for example, that being heavily involved in long-term care has benefited the patient we serve through the decreased utilization of drugs, lowered drug-drug inter-actions and more effective and efficient therapy. That we are involved in these functions means that we are spending time at them -- time which is taken away from dispensing duties which are traditionally viewed as the income generators of pharmacy practice. We must demonstrate to those who would pay us that our services are worth the time we are spending and, for that matter, that the patient, administrator, or third party payer is actually getting more than what he is paying out.

Question #6 - What role does the Pharm.D. graduate have in community pharmacy practice?

Were I a Californian, I would answer this question one way -- here in Minnesota I may have to answer it differently. In California, all pharmacy graduates are Pharm.D.s, and for those B.S.s who come in from out-of-state, there is very little difference in the job opportunities currently available. Here in Minnesota, the graduate of a Pharm.D. program has received extensive specialized clinical training and is, in effect, a therapeutic specialist.

The role of the Pharm.D., therapeutic specialist, graduate in community practice, has two segments. First, he can function in a supportive and cooperative role with the community pharmacist who does not have the benefit of recent clinical education. He can function in a teaching role, assisting the community pharmacist to develop a self study program to help him attain the expertise of the clinical role. He can help establish a resource library and a mechanism of keeping current on the professional, medical and pharmaceutical literature of the day. The second function would be his own practice relating to drug utilization with particular patients in that community setting. I believe we will see the time when a pharmacist is providing those professional services exclusive of a dispensing or distributive function within a community practice setting. As we have found in our own practice in the long term care facility a cooperative and supportive relationship with the community really does work. It has not been our objective to replace the community pharmacist involved, rather to work with him, support him, and help him in his self education process. We have found this to be very successful for the facility, for the community pharmacist, and for an improved level of patient care.

Question #7 - Could you give some ideas of the apprehensions as well as the acceptance of clinical pharmacy by the profession?

It being presumptive for me to respond for the profession, let me share with you some personal concerns I have for our practice and for our profession.

My first concern relates to the need and the development of these new procedures. It is my opinion that the responsibility for the destiny of the profession lies with the profession and not its institutions of education nor its regulatory agencies. It is my personal opinion that the profession is responsible for its destiny, its competencies, and its standards. Educational institutions can provide the educational requirements for development of the individual, and regulatory agencies can assure the public that standards have been met once they have been established by the profession.

It follows, then, that the profession has the concomitant responsibility to develop and guide those programs. A responsibility to aid and experiment in the development of role models - seeking practical, effective, and self sustaining role models. While we most certainly need the vision and the wisdom of our colleagues from academe, educators have the responsibility to function within the profession in seeking these developments, rather than viewing themselves and their particular institutions as sole guardians and prophets of our future. If ours is not a coordinated and cooperative effort it will surely fail.

My second concern relates to the danger I see for fragmentation of our profession. Special interests groups, or groups catering to special interest, within the profession, succumbing to the self appointment process, declare themselves a specialty, in need of specialized education and requiring special certification. The groups soon become politically oriented and motivated, only adding further to the chaos of the organizational structure of American pharmacy. Certainly the activities and accomplishments of a number of these special interest areas may very well lead to the development of a recognizable specialties. APhA has developed the Board of Pharmaceutical Specialties in order that this might be done via an orderly process of development and evaluation within the profession as a whole, rather than rushing into situations which merely compound the confusion. However, if the processes designed for orderly development are ignored and "self annointment" allowed to become the order of the day, the profession justly deserves the chaos which will surely result.

My third concern relates to the standards and the quality of our practice. We must be diligent in our manner of practice so that pharmaceutical services not be perceived as being only necessary for compliance with Federal regulations, nor be tailored to suit pressures or influences of administration or the other professions. Regulations were promulgated when needs were seen in the interes of improvement in patient care. We must reflect commitment to improving patient care in our practice, rather than be a party to the game of compliance for compliance sake.

The educator has a further responsibility which relates to the attitudinal development of the student. The educator must remember that the student is being educated - not ordained and that while the Pharm.D. Student's "philosophical set" may indeed be different from many students in the B.S. Degree program, they are both being educated for the same profession. The clinical graduate who professes to stand on some higher plateau and refers to his colleague in community practive as "just a drug store pharmacist" does little to advance either the practice or the profession.

Question #9 - How does the involvement in patient-oriented clinical pharmacy practice in a community pharmacy equate with still being in business at the end of a financial year?

This question also resolves into two components: reimbursement in community practice, and reimbursement in the long term facility. At the moment there is no mechanism for direct reimbursement for clinical functions, exclusively, rendered in the community practice setting. Advice to a patient which decreases drug use would on the surface appear to reduce drug sales and subsequently reduce the income to that community pharmacist. Unfortunately our profession is still product oriented, with charges the function of product cost rather than fee for professional service. Until such time as we practice with fees relative to professional service, as opposed to mark up on product cost, we will not have the proper emphasis on those services. The long term effects of applying clinical functions in the community setting will reduce drug use. The long term effect is a positive one in that it develops a patient reliance upon the pharmacist and a level of confidence in his/her opinion. Rather than emphasize difference in product cost from pharmacy to pharmacy this will generate an emphasis on the professional service pharmacists offer. Reimbursement then is a result of patient confidence and the retaining of that patient as a customer of the pharmacy. Additionally I believe that in time the pharmacist will be reimbursed for not dispensing a drug. I see this happening first within the frame work of the new HMO (Health Maintenance Organization) concept. Under this program the pharmacist receives a portion of the premium based on a capitation system with a family paying a certain sum annually for all health services. Within this setting cost reductions to the program are achieved by reducing the number of hospital visits and the number of hospital days stay as well as the volume of medication used. As the pharmacist's professional and clinical functions contribute to appropriate drug utilization, he will be compensated for his judgement rather than the distribution of drug products.

Reimbursement in the long term care facility setting has been a difficult problem through these beginning years of the pharmacist role in that capacity. Two systems for remuneration are developing, one in shich the pharmacist charges the facility for clinical and consulting functions on a cost per day per patient basis. The other method being an hourly charge for selected services provided. At the present time there is a mechanism for reimbursement to the facility by the State Welfare Department proportionate to the number of welfare patients in the facility. Whether in the community practice setting, institution, long term care facility, or physician clinic the profession must develop an adequate reimbursement mechanism by which the pharmacist will be compensated for his professional service rather than share a portion of dollars allocated for drug products. Only by achieving recognition for the value of services, with reimbursement for those services, will the professional achieve a standing consistent with the services they are in fact providing.

I have enjoyed being with you. Thank you for your invitation and kind attention and I look forward to further discussion of these issues. Thank you.

# HOW THE STUDENT VIEWS CLINICAL PHARMACY

Ms. Linda Gassman, B.S., Pharm.D. Student, College of Pharmacy, University of Minnesota.

I am "The Student". Many in my position perceive such a title as being synonymous with a curse or at least having a handicap. That is not true in my case. I am excited and motivated about my position as "The Student" and as a result of those feelings, I am anxious to share my ideas with you today on the topic of clinical pharmacy. I must emphasize that what I am about to share with you are my personal opinions and ideas, unless otherwise stated. The comments are based on my personal experiences and should always remain in that context. I do not proclaim to represent the "general opinion" of all Doctor of Pharmacy candidates and would feel a true injustice being done should any other student be held accountable for my comments. I truly appreciate the opportunity to share the next few moments with you, and, if I work it right, I may even be able to accomplish a true reversal of roles here, for my intention is to educate you as to how I, a Doctor of Pharmacy candidate views clinical pharmacy.

First, to establish common ground, I wish to define clinical pharmacy the way I see it being functionally defined for our purposes. Clinical pharmacy is pharmacy practice which is patient oriented. That is how I will refer to the matter.

During the years of development, as well as now, there were and are obviously reactions from every professional and sociological factor coming in contact with the new idea. The others we have or will hear about, but what about the reaction of the pharmacy student?

There is truly an attitude of excitement from the pharmacy student concerning clinical pharmacy. It is a relatively new idea in pharmacy, so the uniqueness of it provides for a portion of the excitement. In addition, the title "clinical pharmacist" has a more professional connotation than does "druggist", the title referred by many a public member. Another area that provides additional enthusiasm is the fact that this situation provides a setting where our technical knowledge of drug therapy can be applied and much greater personal and professional satisfaction is expected from it. There are many pharmacy students who I feel are over educated for community pharmacy as it has been practiced in the past. Now a greater challenge awaits them and they jump at the opportunity to display the type of professionalism they are taught to expect throughout their educational process.

Let us consider another situation. Pharmacy as a profession projects a very insecure image and pharmacy students assume this same feeling as a result of the educational process. I believe the student is able to see clinical pharmacy as a situation where this lack of confidence could be mended. A portion of this confidence comes from the additional professionalism associated with additional activities and responsibilities. This additional responsibility demands more respect, additional professional exposure and additional glory, and rightly so. The fear then becomes one of false security should the individual not return in professional services, the personal benefits that are gained.

So the pharmacy student is obviously reacting in a positive manner. Let us consider two further situations however, where a different type of positive response is evident. Take the frustrated "meant to be a physician but didn't quite make it to medical school" student, for example. This student now has an even more satisfying avenue to escape from his frustration. Now he can command the same title, exist in the same atmosphere and depending where he is located, can even share the same responsibilities as the professional of his dreams. Or consider those individuals that aren't quite sure why they are in pharmacy to begin with or where they are going in the profession. Clinical pharmacy is one more aspect that is defined vaguely enough so these individuals are comfortable in the uncertainty of it all. Perhaps for these people, we are replacing the counter we hid behind as community pharmacists with the uncertainty to be found in clinical pharmacy. Although the last two examples serve as unpleasant realities, I believe we must learn to identify the different types of enthusiasm being displayed toward clinical pharmacy.

Let us proceed one step further in reviewing students' attitudes. We know they are enthusiastic about the general idea, but do they accept clinical pharmacy as it is being presented in colleges today? In a majority of cases that question is answered with further questions, by the student himself. Such as, just what _is_ clinical pharmacy and how _is_ it being presented? Students constantly complain that no one knows exactly what this new idea is all about and therefore no one has the right to expect the student to be good at it. Those students are falling short of their responsibilities. I believe that if an individual has a grasp of what they expect out of pharmacy, how they want to apply their knowledge personally and what the endpoint in their profession is going to be, then clinical pharmacy is a very motivating and exciting experience. It is exciting for the very reason they fall short of mastering it, that the field is open and the limits to a pharmacists involvement clinically, is yet to be applied. Pharmacy students are generally programmed throughout their undergraduate training to be "spoon fed", to think only as far as a structure or definition will take them. Application, abstraction and extrapolation of ideas are not learned in the majority of situations. As a result, along with clinical pharmacy being exciting because it is new, it is also very frightening and personally intimidating. After all, many of these students are being held accountable, I mean really accountable for the very first time when put into a clinical situation. I can relate to the feeling very extensively. No longer does the large classroom protect the inability to communicate with one another, no longer are side effects only seen as nausea, vomiting and diarrhea, but are heard as cries of pain and non compliance. These situations must be dealt with and without an experience base or realization that they even exist, how can one be comfortable performing the task? The philosophy of teaching in the undergraduate program must progress from one of regurgitation of information to the application of knowledge.

Personally, I see clinical pharmacy developing in basically the correct manner. The pharmacist is getting involved in patient care where his influence is primary instead of secondary, the pharmacist is educating others in an area that he has mastered through five years of college and the pharmacist is finally demanding accountability from health care practioners that has never been done before, all are steps toward better patient health care - hopefully the ultimate goal for all pharmacists. However, to ignore the problems that are evident, would be less than responsible. The problems that do arise in clinical pharmacy are a result of the following situations:

1. - The individual pharmacist has not determined in his own mind what his intentions, goals and expectations of functioning in a clinical setting are, so is obviously unable to communicate them to anyone else.

2. - There is not enough time allowed for setting up initial groundwork and intentions are misinterpreted as a result.

3. - The pharmacist does not let his knowledge base limit his expectations of involvement and conflicts of interest develop.

4. - The role model set out does not perform competently and is incapable of justifying his presence both professionally and economically.

5. - The pharmacist refuses to learn from educational experiences commonly referred to as mistakes and subsequently suffers from the same syndrome we as a profession accuse the physician of uniquely acquiring.

As a result of my comments so far, I hear Mr. Retail Pharmacist and Dr. Pharm. D. asking me, "Is she talking about him or me? Is she referring to the Bachelor of Science Degree graduate or the Pharm.D. Graduate?" My answer is that I am talking to both of you, so both of you, please listen. The retail pharmacist has often claimed that the Pharm.D. has no right to demand the title of doctor, no right to make him look like a second rate practioner, no right to demand more professional attention and on and on. There is obviously an unfortunate misunderstanding between the two factors of pharmacy. A misunderstanding that could be alleviated should a few assumptions be accepted by both factors. First, the term "clinical pharmacy" is not completely holy. The term does not assure its participants of being competent and infallable, but instead the word has come to be a non descriptive term that is used for a lack of better terminology. Secondly, this "clinical pharmacy" has to be practiced by both the retail and the Pharm.D. individual. It is not an "either", "or" situation. The distinction between the two factors is made by the physical environment, the type of patient being dealt with and the ends to be accomplished. The Pharm.D. student, in my mind, is a specialist, trained and performing beyond the accomplishments of the Bachelor of Science Degree graduate. There is no confusion between the two whatsoever as I see it. The Pharm.D. has control of the science of disease states, laboratory medicine and its relation to drug therapy, application of pharmacokinetic principles in monitoring dosage regimens. He specializes in cardiology, connective tissue diseases, immunology, oncology, hematology, nephrology, administration, or whatever, he is never utilized in a position where a Bachelor of Science Degree graduate could function equally well. If put into that situation, he becomes redundant, he imposes on their professional responsibilities and he initiates hostility amongst the members of his profession. None of these goals, has he the right to achieve.

In order to keep my faith in the profession, I have to assume that the initial intent of the Pharm. D. Degree was not to cause the intraprofessional problems that it has caused, but was meant to be utilized in the manner I mentioned earlier. I see it as unfortunate, however, that we are not training the majority of Pharm.D. graduates across the country to be specialists, not at all. We are training them to be retail pharmacists, to fill the positions in chain pharmacies, and unfortunately to instill hostility in the profession. If we would have continued to produce quality individuals that deserved the title of doctor due to their specialized expertise beyond the basic pharmacy education, the hostility would not exist. It would be advantageous if those individuals deciding if one degree, two degrees, or three degrees are the right thing, would first decide what it is they wish to accomplish by their decision, what they are willing to sacrifice in the process and whether the benefit is going to be worth the sacrifice at all. I believe they owe that much to the Profession.

You have heard me speak often to the issue of Pharm.D. graduates being granted the title of doctor. I firmly uphold that this sole factor is the root of the discontent that we have seen in our country since the institution of the Pharm.D. degree. Take a look at the real problems with one degree or two, with retail vs Pharm.D., really, with the egotism of one aspect being compared to the inferiority complexes of the other aspect. The difference is in the title. The question that often enters my mind as a result of this is whether the resulting problems within the profession have been worth the price we have had to pay for the title of doctor.

I mentioned earlier that if we are going to call part of the profession doctors and the other portion of it misters, then we should make sure the doctors are very worthy of their title. I also made the accusation that the Colleges of Pharmacy are not necessarily training their Pharm.D. candidates to be these types of specialists. So your next question should be; what is the correct means of educating and training this group of professionals? I obviously don't claim to have all the answers. There are areas, however, in the educational process, that I have seen as a Pharm.D. student that need reorganization or changing to assure that we are getting the type of product we wish to produce from the program.

My first step would be to assure that the most desired individuals are to become a part of the Pharm.D. program. This would be done by measuring academic accomplishments, measuring factors of motivation, professional and personal awareness, the level of professional and personal maturity, communication techniques, and by becoming familiar with the personal goal expectations. This would all be a part of the selection process. I hear constant mention of the fact that there is not enough, good role models for Pharm.D. candidates to follow across the country. I would emphasize the "good" and not the "enough" portion of that statement, and this could be controlled on entrance of the student to the program. Once the Pharm.D. student has been selected he must be processed through a program that is going to make him the best practioner available in his particular interest area. For this type of program I refer you to the Kansas City model. As a result of my experiences and my expectations, this model proves to be a very good basic program. I say basic because there has to be a much greater emphasis on communication and education skills among this group of professionals. I see it invariably... these academic geniuses are put into a real clinical situation and they can not communicate their information to anyone. It becomes so obvious that the power of persuasion and manipulation, the real art of communication, are all just as important as understanding the Mechalis Menton Principles of salicylate kinetics, when trying to get this particular point across. And look how the Pharm.D. curriculum has ignored the aspect of acquiring the talents of a good educator. The ability to educate is not innate, it has to be taught and learned just like biochemistry and calculus, so then why is it being ignored in a curriculum that is itself dependent on it?

In addition to selecting the correct individuals and putting them through the most thorough didactic program, I would begin their clinical exposure the same day they begin their didactic work. Not enough can be said to the issue of emphasizing clinical exposure. There is not a book in the library that cries and screams, or a blackboard that does not comply with its medication, or a classroom that can act out an anaphylactic type sensitivity reaction. There is just no teacher like the real experience - we have heard it so many times. I believe a curriculum that does not give clinic exposure throughout the entire Pharm.D. program is not fulfilling its responsibilities to the student, for the optimal learning situation is being part of the situation itself.

Another factor in assuring that these Pharm.D. graduates will be the most competent has to do with the faculty that is executing this adequate didactic and clinical experience. This aspect of the program has been most frustrating to me. I alluded to a strict, selective process occurring to insure only the most desired individuals entering the Pharm.D. program, I advocate even a stricter one for the selection of their educators. As I mentioned before, the ability to educate is not innate. So often when reviewing Pharm.D. curricula, I am bombarded by minimum standards and minimum behavioral objectives to be met by every student before they progress onward to the next phase of their educational process - but never do I see minimum objectives that are being maintained by the Faculty in these settings. I believe this to be very important and very helpful for the faculty member involved. What is lacking in my opinion? What do I wish to see in those that lead me through my Pharm.D. education? Let me explain.

What about security? I have found security and confidence in Pharm.D. clinical faculty to be an exception, not the rule at all. I am not only referring to professional security but personal security as well. Why the defensiveness even amongst ones own profession? I realize we are in an era where justification and defense of ones position is required daily by the public, the nurses, the physicians, but why the response among our pharmacy colleagues?

I also want an educator to lead me. Not someone to continue the spoon feeding process - not at all. Nor am I saying give me a role model. I am aware of the drastic shortage of adequate role models across the country. This is a neccessary shortage ofr the time being, for we are obviously in the early years of the development stage. The problem is that we must compensate for the lack of these role models. I feel we have adequate people available relaying the didactic pharmacokinetics, etc., are all being well taken care of. However in the abscence of individuals showing the student how to apply the information, there is no one teaching the student the correct way of applying the knowledge once he begins his clinical experience. So many times the faculty have difficulty relaying the application of this knowledge. The little geniuses that colleges of pharmacy are calling doctors too many times belong in the encyclopedia section of the medical library and not on the hospital wards with real patients and real physicians. We need educators who can recognize individual talent, interest and motivation and can make it work for the college, the profession and the student. It is very important to have someone capable of asking the question why? You may respond that anyone is capable of questioning the student about decisions, motives and so on. I uphold that they must be able to ask the question on an individual basis and must be able to respond to the individual answer. There aren't very many who are willing and able to respond to questions unless they know what the answer is before the question is asked. What we need in a program such as the Pharm.D. program are those that can ask and respond to the following questions: Why are you here to begin with? Why do you think you can do a better job than anyone else? Why are you so insecure when put into the clinical situation? Why are you so defensive in your attitude? Why the implications of negativism in your attitude toward learning? Why are you motivated, why aren't you motivated? Why do you succeed at times, why do you fail at other times? Why do you get the answers you do? And why should anyone listen to you at all? All of these questions have to be asked of me before I can succeed at anything at all, professionally. Just think how fantastic it would be if the people who were able to influence the answers, were the ones to ask the questions! If this were the case, I know we would have a greater abundance of those good role models we spoke of earlier.

Let us assume that I have selected the most desired student, put him through the best didactic and clinical programs, under the direction of the most astute educators, what would I do with him now? The first thing I want to do is to get him licensed. I feel it is mandatory to assure the public and other health professionals that he is competent and legally able to practice. Practice what? Not medicine and not retail pharmacy as it has been traditionally practiced. I believe the Pharm.D. should be examined and licensed according to what he is taught and is able to do. I am advocating a specialty examination for this group of professionals. In addition to being licensed, the Pharm.D. should be held legally accountable for the transfer of his information and application of his knowledge. If he is good enough to practice, then he is good enough to be held accountable for what he is practicing.

You should at this point, be insisting on knowing what this individual is going to contribute to the health care team. Unfortunately I can't tell you what he is going to contribute, only he can do that. However, I can tell you what I personally hope to contribute and it is only meant to serve as a suggestion of what one Pharm.D. will do with her educational experience. I will utilize my second Pharm.D. year of clerkships to gain clinical experience in a number of areas, for example surgery, psychiatry, medicine, pharmacokinetics, ambulatory care, oncology, cardiology and many others. I will emphasize my studies in the area of pediatrics, for that is where my principle interest lies. When I am finished I hope to secure a position in a pediatric facility where I will function as a therepeutic specialist. I will not function as a medical librarian in this setting, however. I will educate, truly educate, patients and health practioners as to the proper application of therepeutic knowledge. For example, in the areas of dosing and monitoring dosing during various disease states, inservice training programs, ambulatory care problems and hopefully many more. In addition, I hope to put a second emphasis on administration of the Pharm.D. area. I have seen a lack of directing and coordination many times in the area and because I am now a part of it, I believe I am in a position to do just that.

Does it all sound very theoretical to you? If so, please look harder and speak to more individuals, for everything I have suggested can and is being done across this country today.

I thank you for your attention. I hope my comments are not seen as in agreement to your own or contrary to your own, only in addition to your own, for that is how they will function optimally. Thank you.

# HOW THE OBSERVER VIEWS CLINICAL PHARMACY

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I have been asked to present my views as an observer but I must stress straight away that I have principally concerned myself with concepts and attitudes. I have read, observed and listened about developments in pharmacy, focusing particularly upon relationships between pharmacists and physicians. I took this approach because I believe that much of what will happen in pharmacy over the next decade will be largely determined by these relationships. However, it is important to remember and to always consider that the professions of pharmacy and medicine cannot develop in isolation; the problems which we face in drug use have not been created by any one group in society and solutions cannot be sought by only one group without the involvement of others.

From my studies I will attempt to give you an overview of how I see developments in the United States of America. This may help you to put clinical pharmacy into perspective, because it is important to realize that changes taking place in pharmacy practice in one country will effect pharmacy practice in another.

My overall impression of pharmacy in the United States of America is one of turmoil. From its practitioners and academics, from its institutions and societies, from its schools, colleges, and dispensaries I sense a tremendous upheaval. There are fears, threats, convictions, and confusions. Yet from out of these is arising a clear and committed direction for the future of pharmacy away from and beyond the point of dispensing and into patient care and drug treatment outcome. A direction which will take pharmacy practitioners to the patient's bedside (clinical), emphasize their educational and advisory role in the community, and involve them in direct confrontation with what has traditionally been the sole prerogative of physicians - therapeutics (the drug treatment of disease).

This change is being fought under the flag of "clinical pharmacy" which can mean different things to different people but its overall message is that pharmacy education intends to become patient-oriented and that many pharmacists have convinced themselves in the process of trying to convince others that they can make more optimal the use of drugs in society.

It was thus appropriate that this message was formalized and given approval by the publication of the Report of the Study Commission on Pharmacy in December, 1975.[1] The report "Pharmacist of the Future" (Millis Report) gave credence to what was already happening and highlighted the critical role of the educational institutions in future developments. Many pharmacists looked to the Millis Report for clear cut definitions and directions but they received only general guidelines. This was a sensible response by the Commission considering the background of confusion and lack of cohesive commitments by the professional societies, groups and educational institutions.

What then is clinical pharmacy? The term not only describes a wide range of ideas, attitudes and activities, it also describes a force for change.

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In commenting upon this force the Millis Commission was obviously considering clinical pharmacy which it perceived at that time "only as a common idea - an emphasis upon drugs as they are utilized by patients". But things are changing rapidly; what the Millis Commission saw as concepts are now commitments, what were philosophies are now practices, what were fragmented ideas are now an ideology, and what had developed in scattered colleges is now being developed nationwide. Furthermore, of interest and concern to those of us from abroad, the practice is spreading internationally. Already countries as geographically and culturally diverse as Canada and Saudi Arabia are setting up clinical pharmacy programmes and even at that most conservative of gatherings - The 1976 Annual British Pharmaceutical Conference - the term clinical pharmacy has found its way into the programme.

At this meeting in Minnesota there are pharmacists gathered from countries all over the world and so we must realize and recognize the internationalism of the clinical pharmacy movement. This has important implications for those of us from Europe whose countries are members of the European Economic Community and whose directives move us towards harmonization and unicity of basic education and training.[2]

During your visit to Minnesota you will be seeing many and varied types of clinical pharmacy practice. And I am sure you will be impressed by the youthfulness and enthusiasm of the clinical pharmacists running these services. I often refer to them as pioneers because they are having to hack out their own roles in what is often a hostile and uncharted environment. Sometimes I see them as revolutionaries fighting their way from ward to ward and clinic to clinic, using their knowledge and skills as weapons against those most deadly of enemies - prejudice, bigotry and professional prerogatives. Comments from three chairmen of clinical pharmacology divisions will give you an indication of these - "Every child likes to play at doctors and so do pharmacists", "What can those pill counters really know about drugs", "Clinical pharmacy - well that's just an aborted fetus". Some will be sacrificed in the "revolution" and some will succeed. Some are ill-prepared and many of them lack guidance from their commanders - members of the college of pharmacy faculties. This lack of direction has occurred for one very good reason: members of faculty have traditionally been product-oriented rather than patient-oriented. This has meant that, no matter how enthusiastic for clinical pharmacy, they are unable to act as role models because they lack any sort of clinical experience. Some are not even pharmacists and have little appreciation for past problems and present and future directions. It has also meant that in designing the clinical content of curricula, pharmacy school faculties have been unable to draw upon clinical experience. Consequently most schools have had to rely on clinical pharmacy graduates* to begin to define a role so that their clinical pharmacy students could be taught. As one student said to me "they (the clinical pharmacists) really don't know what their own role is let alone teach us about it." In such an insecure situation it is not surprising that some clinical pharmacists have identified with physicians and are now acting as physician's assistants. A situation which may extend the professionalism of the of the physician but could deprofessionalize the pharmacist. I do not wish to labour the revolutionary description but it is more than evident that as some stage there must be negotiations between the leaders in medicine and pharmacy and those ultimately responsible for spending the taxpayers money - i.e., government.

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* Recognition must be given here to graduates from San Francisco.

To understand more fully how the clinical pharmacy movement developed it is important to ask why did it occur. I see two principal reasons: First there was a growing discontent among many members of the pharmacy profession that their knowledge and skills were being underutilized in the routine procedures involved in the dispensing of drugs. They began to express criticism that pharmacy education was largely irrelevant to dispensing practice in which 75 percent of pharmacists are involved in the community and 12 percent in hospitals. Some even suggested that most of the dispensing activities could effectively be taken over by technicians, trained administrators and shop managers. This discontent or as Millis[3] calls it "divine discontent" lead to a search for a re-definition of the role of the pharmacist which should and would take into consideration his knowledge about drugs and their effects upon humans and involve him in a health service.

On its own this discontent may have faded out but the time was right for an extension of the pharmacist's role into patient care because there was a consensus amongst health care professionals and society in general that drugs were not being used optimally by physicians and patients. Although it is almost impossible to state what is the optimal use of drugs in society this consensus spread and was based largely upon reports and criticism about the prescribing habits of physicians and drug usage by patients. This consensus formed ammunition for the activitists in pharmacy who began to use it in their arguments for the need for pharmacists to be more closely involved in the drug treatment decisions of physicians and supervision of patients' drug use.

The suboptimal use of prescription drugs became directly related to poor prescribing habits of physicians,[4] poor education of physicians,[5] the gullibility of physicians to outside influences,[6] and the promotional activities of drug companies.[7] Yet many of these inferences remain unsupported by scientific evidence[8] and have been used and misused to proffer the claims of those with vested interests in therapeutics - i.e., clinical pharmacologists and of late clinical pharmacists. As a consequence of these consensuses, the physician's ability to prescribe drugs rationally has been called to question. For example the Task Force on Prescription Drugs (1969)[9] noted that observers had reported a lack of knowledge and sophistication in the proper use of drugs as perhaps the greatest deficiency of the average physician today. The report concluded that much of the difficulty comes from "The constant insistence on the idea that the average physician, without guidance from expert colleagues, does in fact possess the necessary ability to make scientifically sound judgments in this complicated field." In 1972 in "A Study of the Role of the Clinical Pharmacologist in Direct Patient Care"[4] it was stated "The inability of the prescribing physician to keep abreast of the demands of modern drug therapy and to make informed judgment on the risks and hazards of the multiplicity of drugs has been well documented by many authors and review groups."

Focus truned onto the physician's education and it was found that over the past decade ther had been in general a decreased training of medical students in pharmacology and drug therapy in the United States.[4] In Great Britain a study by the Medico-Pharmaceutical Forum (1975)[5] found that the proportion of time devoted to learning about drug therapy was considerably less than is warranted by the importance of the subject to modern medicine. This study also found a disproportionately low concentration on drug therapy in postgraduate education of physicians.

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What has become evident over the past decade is that despite an increasing concern about suboptimal drug use and poor physician education this is not being reflected in undergraduate and graduate teaching of physicians. The hopes for the expansion of clinical pharmacology following the thalidomide tragedy have not materialized. Pharmacology remains a Cinderella of the medical profession, its share of curriculum time remains small and in some medical schools it has got even smaller with the development of trackings and electives. Most clinical pharmacology units depend almost entirely on research and training grants[10] and would close tomorrow if funds from the pharmaceutical industry and government were withdrawn. Clinical pharmacologists have become overstretched in the fields of education, research and service and much needed research has suffered. Education is failing as students are not offered or do not choose clinical pharmacology electives (in fact, some medical schools do not even offer an elective) and the service role is questionable since clinical pharmacologists are usually to be found attached to some high powered university hospital department when there is a much greater need for such services out in the district hospitals, long stay hospitals and in the community health centers - i.e., places where pharmacists are already available. As one clinical pharmacist said to me "What's the use of the clinical pharmacologists trying to influence the prescribing of internationally recognized experts, when around the corner they're turning out family practitioners who have never received any formal teaching in clinical pharmacology and therapeutics."

As for other factors which influence the prescribing habits of physicians a review of the medical and scientific literature indicates that our knowledge of such factors is very limited.[7] The relative importance of different factors are unestablished but the available literature and common knowledge suggest that the drug companies are one of the major factors influencing the physician.[7] It is this influence by the drug companies which comes in for comment by the Millis Commission. It observes that most knowledge generated by drug companies is directed towards the prescribing physician, little going directly to pharmacists. Furthermore, this dissemination of information is confusingly tied up with the promotional activities of drug companies and comes from a less than disinterested source (each prescription written represents a sale). It is this relationship between sales promotion and the dissemination of information which has become a principle focus for criticism of physicians' prescribing activities.

Studies of the use of prescription drugs by patients have indicated much wastage,[11] a high degree of non-compliance to physicians' instructions,[12] poor communication between physician and patient about drug treatments,[13] and in general a poor level of understanding among individuals about the benefits and risks of drugs.

Several gaps are thus evident in the use of drug treatments in health care - gaps in the application of available knowledge about drugs to the treatment decisions of physicians, gaps in the education of medical students and physicians, gaps in the education of patients, gaps in our knowledge of how physicians and patients use drugs and a major gap in our knowledge about the overall benefits and risks of drugs to society.

In addition to these consensuses and the claim by pharmacists that they could make drug use by physicians and patients more optimal, there are discontents amongst pharmacists which relate to power and status. Many of them are concerned with comparisons of power and status among physicians and pharmacists. "We have always had this Uriah Heep attitude toward physicians--Perhaps if we were all called doctor--We were always taught never to question the decision of the omnipotent physician--We can't prescribe but any untrained assistant working for a physician is allowed to, because the physician just signs the prescription form". These attitudes are often evident whenever groups of pharmacists gather because a frequent topic of conversation is about "the pharmacist/physician interface". Techniques and maneuvers are discussed on how to get the physician on the pharmacist's side. It really appears that having the blessing and approval of the physician is a great wish of many pharmacists. But of course relationships between physicians and pharmacists are going to determine much of what will happen and so it is important to give a warning at this stage. Physicians are being subjected to too much criticism, they feel threatened and they dislike direct challenges of their drug treatment decisions. Drug utilization reviews, chart reviews and other post-hoc procedures can look like policing and produce resentment. It is important that pharmacists stop overplaying the bad prescribing habits of physicians and develop a constructive approach by trying to help the physician at the treatment decision stage. This requires communication and the pharmacist acting as advisor and not merely as an informer. There must therefore be more to drug information centers than just providing information. This is probably why some have failed. The staff must be available to give advice and to make judgments by communicating with the physician. "We often find that if you go out of the drug information center and go and talk to the physician you find he didn't ask the right question, he really needed help in selecting the appropriate drug". For this reason I think Drug Information Centers should be called and act as "Drug Treatment Advisory Centers". By this I imply that the pharmacist must have knowledge of the patient and his/her disorder as well as knowledge of the drug if he is to act in a truly advisory capacity and make judgmental decisions.

If the pharmacist is to become the drug expert in society then the ability to communicate should become an important part of his training - he must be able to communicate with physicians, patients and others. He must learn the language of medicine and share in its body of knowledge. His whole training will need to shift from a physio-chemical base to a bio-social base if he is to function effectively. There will, in future, have to be much more relevance between what he is taught in pharmacy colleges and schools and what and how he subsequently practises.

Along with concern about physician/pharmacist relationships pharmacy has begun to define its service role - as a knowledge system which renders a health service by concerning itself with understanding drugs and their effects upon humans. If fact provision of a service and the desire to be more professional have become synonymous in the eyes of many pharmacy educators and practioners. And of course the service ideal is an important part of the professional ethic which justifies social approval. A difficult target however, when the crass commercialism of some community pharmacists is considered - note the recent clearing of competitive drug advertisements for drug prices (The Wall Street Journal, Tuesday, May 25, 1976).

The desire to give a service is only part of the game of professionalisation which has developed - we can observe the alteration of names (clinical pharmacy), the alteration of titles (doctor of pharmacy), and the development of a specialized body of knowledge to be used in service (applied pharmacology).

These are games which must be played if those of you from other countries wish to increase the professionalization of pharmacy.

In order to rescue the service ideal from the commercialism of the "druggist" Millis envisages increasing the institutionalization of the pharmacist into health centers and hospitals. This will lead to the inevitable bureaucratization as administration becomes increasingly based on rationality and less upon tradition and personal considerations. Apart from this increasing bureaucratization and institutionalization of what Millis already regards as the most controlled profession in society no other alternatives have been suggested as to how to develop community pharmacy. Yet surely there are important roles for pharmacists in the community in health education, primary health care, and in preventative medicine. There is urgent need for colleges of pharmacy to examine the education and training of pharmacists for community practice and also of those who wish to act as entrepreneurs in the community. Or do they see the death of these entrepreneurs as clinically trained pharmacists opt for institutions? Would not this cause the loss of an easily accessible professional who in combining his business with his profession has successfully provided a patron service to those who sought his advise.[14]

One way of improving the service role of the pharmacist in the community would be to re-classify certain groups of prescription drugs in order to create a new intermediate class of non-prescription drugs available exclusively through pharmacists. Because here is an area in which the pharmacy profession could demonstrate to the public that its members have the knowledge to prescribe these drugs and that the profession can exercise its own controls and standards over its members, in other words, be truly professional.

As for institutional pharmacy, increasing mechanization and computerization will inevitably call for more supportive technical personnel and business type training. This will lead to further bureaucratization which may not be incompatible with the degree of professionalism to which pharmacy aspires but which will raise all the problems of professionals working within an organization with other professionals. The real issues which are clearly developing are about control, status and power. This is becoming evident in the relationships between staff (hospital) pharmacists and clinical pharmacists. Whilst the term clinical pharmacy has become successfully used as a political weapon (even at Federal level) it may be a double edged sword. Clinical pharmacy as it is now developing will divide the profession into those responsible for the product and those responsible for the patient. Already patient and physician contact is creating an elitist attitude amongst clinical pharmacists in hospitals who are busily acquiring all the attributes of specialists and may I say it - physicians. Some have different salary scales, different contracts and different offices well away from the dispensing pharmacist, and some have that seemingly all important title - doctor! ("They're too busy playing doctors to come down to the pharmacy": quote by a staff pharmacist.)

The fundamental problem facing those institutions (hospitals, group medical practices, etc.) in countries where their economy is poor (e.g., Great Britain) is whether one pharmacist should be trained to carry out both roles - drug distribution and clinical pharmacy. In this dual role the pharmacist would have to rely on technicians to carry out many pharmacy duties - made very much more tedious by the introduction of unit dose dispensing and other innovations.

Yet are there dangers in such a dual role? If the dissemination of information about drugs is to be done by the same person who is responsible for ordering and dispensing drug products then one role may be influenced by the other. This would leave the dual role pharmacist in a highly vulnerable position when dealing with sales pressures from drug companies. If the hospital clinical pharmacist were removed from the duties of having to order and supply drug products then surely he would be able to act in a more objective way and be more highly motivated to make drug use more rational. This I see as an important area to keep an eye on because there is already much discussion amongst the drug companies about how to improve their relationships with pharmacists. When it is realized that one clinical pharmacist may influence the drug treatment decisions of several physicians, that pharmacist is going to find himself a target for the promotional activities of drug companies. If he is to remain objective and be well motivated he may need relieving of any cost commitment to the pharmacy of products ordered or dispensed. This again is a dilemma to be faced in community pharmacy. But the argument of some of these pharmacists is that they would merely support the drug treatment decision of the physician - and not influence it.

On this question of supporting physicians' treatment decisions - problems are always raised in my mind when I have observed clinical pharmacists counceling patients about the taking of prescription drugs. Such activities would be commendable if we could be assured that the drug treatment decisions of the physicians were always rational - but sometimes I have seen clinical pharmacists merely adding support to non-rational decisions of physicians. Surely the point here is that the pharmacist of the future must act to educate both patient and physician - he sould not isolate one group for special education. From a manpower point of view would he not be better educating the physician?

On the point of physician education it could be asked whether it is beyond the means of medical education, peer group reviews and modern communication technology to get physicians to acquire and apply appropriate knowledge about drugs and their treatment. In answer to this I would suggest that there appears to be a limit to how much information in whatever form or quantity can compensate for lack of knowledge and motivation to learn about drugs, their uses and effects. The physician is principally a problem solver and it is clearly not possible for individual physicians to fully evaluate the mass of information about new drug preparations for themselves let alone keep up to date with all the latest findings in clinical pharmacology and clinical toxicology. Yet it is upon the application of knowledge determined from such studies that rational decisions about drug treatments should be made. But the physician lacks motivation to learn about drugs because the whole of his education and training have focused upon diagnosis. In highlighting the need for additional reliable teaching in drug therapy the Medico-Pharmaceutical Forum identifies this problem in medical education - "the traditional attitude that pathophysiology and diagnosis of disease are of overriding importance and that therapeutic aspects are secondary."[5] It was Osler in the last century who stated that there are three things to the practice of medicine - diagnosis, diagnosis, and diagnosis.[15] This Oslerian philosophy still continues in medical schools despite the fact that in the last three decades there has been tremendous advances in therapeutics. As the Medico-Pharmaceutical Forum report observes "The medical profession does not appear in general to have adjusted to the speed of change."[5] The report argues that "ideally, the student should emerge from his medical school with a sound knowledge of basic and clinical pharmacology and with a constructive attitude which recognizes that it is in relation to medicinal therapeutics that continuing education throught his working life is most necessary." Yet there is no evidence that medical schools are producing such a constructive attitude. Furthermore, evidence that undergraduate education is related to future good prescribing practices is not convincing.[7]

Reports in the medical and scientific literature suggest that prescribing physicians often lack knowledge of the basic principles of clinical pharmacology. Yet if we consider that the principal concerns of medical practice are diagnosis and treatment and that most treatments involve the use of drugs, it is not difficult to accept that clinical pharmacology should be an important base for the whole of medical practice. However, it appears that this is not always recognized and as a consequence those responsible within the medical profession can be rightly charged with failing to maintain a reasonable standard of basic education for medical practice.

Such failure has made the prescribing physician vulnerable to those activities of the drug companies which principally seek to influence his prescribing practices. Also with increasing consumer awareness it is not surprising that a consensus has developed that drugs are being prescribed suboptimally by physicians. This is now accepted and has become common knowledge; to set up evaluative studies of the appropriateness and safety of physicians' drug prescribing would be too costly in time and money. Furthermore, studies which describe the phenomenon of drug prescribing will produce few factors which can be modified,[7] they may in fact make the problem more complex.[16]

Against such a background it seems appropriate that pharmacists should be educated and trained to become more involved in the self-treatment decisions of individuals and in the treatment decisions of physicians. Learning about drugs and their effects on the body in various physiological and pathophysiological states should form a major component of his education. Furthermore his knowledge of formulations, dosages, forms of administration, pharmacokinetics and individual responses to drug therapy will make him unique to health care. In addition if he is to function as society's applied pharmacologist he will need to view health, illness and treatment within a social context and learn the techniques of social scientific enquiry.

In commenting upon the future role of pharmacists I have purposefully avoided the term health team because this remains only an ideology as a result of the struggles for power and status of the various health care professionals who claim recognition within the health care service. Certainly many centers I have visited were in the grips of power struggles which were far removed from the interests of the consumer either as tax payer or patient. Future pharmacists will inevitably be involved in these struggles and so they must develop and use their unique body of knowledge in applied pharmacology (which will include medicinal chemistry and pharmacokinetics) otherwise they could loose their identity as pharmacists. They should try not to feel threatened nor should they threaten. Already some clinical pharmacologists are calling pharmacokinetics just "a toy", "a gimmick", "simply an extension of drug distribution to the cell" and therefore it must be seen as only a part of the pharmacist's total body of knowledge about drugs, their risks and effects in humans and their use by individuals and in society.

You can see that on the service side the functions of the clinical pharmacologist and clinical pharmacist are very similar. Many of the problems we are facing have stemmed from this word "clinical". It has become somewhat of a status label - i.e., "I am really a physician" and clinical pharmacologists are keen to be seen as physicians (particularly in Great Britain where to be a physician in charge of hospital beds is the great symbol.) This is really because the role lacks definition and the practice crosses clinical boundaries, so clinical pharmacologists have always felt a need to be "accepted" by other physicians. And now we see clinical pharmacists taking on the title "doctor" and also seeking recognition from physicians. Perhaps it would be better if Gold[17] in 1952 and Gaddum[18] in 1953 had adhered to the term human pharmacology and then we would not have had this desire to be a physician as well as pharmacologist. I think this has created a trend for the worse so that clinical pharmacologists have become involved in service to the detriment of the scientific side of clinical pharmacology. Certainly from my observations some clinical pharmacology fellows are carrying out service roles rather than learning pharmacological methods of scientific enquiry. We have precious little information about the actions and effects of many drugs we use in various physiological and pathophysiological conditions of patients - particularly in pregnancy, infancy and old age. In addition we lack information about how drugs are used by patients, the effects of drug intervention on the outcome of many common disorders, and as I have already stated on the overall benefits to risks of most groups of drugs we use. These latter problems will be tackled by future pharmacists. It is to them that we will look for guidance on drug use, for studies of drug utilization and for feedback of information so that drug treatment decisions can become more rational.

I see future pharmacists as primary advisors, educators and monitors on drug treatments. They will continously feed their findings back to clinical pharmacologists (some of these will be physicians - some will be pharmacists - the term clinical should no longer imply a medical qualification) who will interpret and correlate them with their pharmacological studies. The clinical pharmacologists will act as consultants to a group of clinical pharmacists and I see such services on a regional basis with the clinical pharmacologist located in the main hospitals. The clinical pharmacists will be located in main hospitals, district hospitals, community clinics and group medical practices - the community pharmacist will also be clinically oriented. Such a plan will require close cooperation between clinical pharmacists and clinical pharmacologists and today's clinical pharmacologist ought not to see clinical pharmacists as a threat but rather as a means of extending quality drug therapy services to a whole community. This will require the involvement of pharmacists in the education of medical and pharmacy students, physicians and pharmacists and other health care professionals and patients, it will involve them in research and it will put the principle burden of service onto them.

I also feel that clinical pharmacologists must be located within pharmacology departments which themselves must not be isolated from biochemistry, physiology and genetics. This sort of close relationship would then ensure the most effective communication network for knowledge generated about the actions and effects of drugs in humans to get through to those involved in education and service.

During my travels I have listened to discussions about the physician eventually being the diagnostician and the pharmacist being responsible for drug treatments. These sort of comments are dangerous because they treaten the physician unnecessarily, and they are premature because pharmacists have not yet established themselves in service (the majority of clinical pharmacists in practice are funded by colleges of pharmacy, the various institutions having not yet decided to pay directly for their services). They are also naive because in the area of drug treatments as practiced by physicians diagnosis and treatment are often inseparable and will be more so in the future as physicians learn how to help patients in a more holistic way.

Away from physician generated drug treatments, the pharmacist will be involved - advising on self treatments, and in the diagnosis and treatment of commonly occuring medical emergencies and commonly occurring disorders - i.e., in the community the future pharmacist will take on primary health care, preventative health care and educational roles. This should help individual patients, physicians and society by creating informed use of drugs.

Finally let me stress five points I have made so far and then draw some conclusions. First, it is now common knowledge and we ought to accept that there is less than optimal use of drugs by physicians and patients. To attempt to test this knowledge would be too expensive in time and money. Second, there is a gap between the generation of knowledge about drugs and the application of this in our everyday use of drugs. Third, the education of physicians in drug use is principally in the hands of the pharmaceutical industry and this is tied in with its promotional activities. Fourth, it must be accepted that the individual physician cannot keep up-to-date with all the advances in drug therapy and is almost conditioned not to do so by the traditional attitudes of those responsible for medical education. Fifth, the problems we face have not been created by any one group and will not be solved by any one group in society.

Bearing these five points in mind and having studied the use of drugs by physicians and patients for the past eight years I am convinced that there is need for an intermediate agency between those who generate knowledge and those who use drugs. The obvious intermediary is the profession of pharmacy whose members should be involved in the generation, collection, interpretation, validation and dissemination of information about drugs and their actions and effects in humans in order to make more safe and appropriate the use of drugs in society. In addition, they should monitor drug use and could be called the bio-social pharmacologists of society.

The future will depend upon conflicting economic and professional interests, particularly those between pharmacists and physicians. If the latter do not cooperate with each other then all I can see in the future are increasing governmental regulatory measures being applied to the prescribing physician, the pharmaceutical industry and to pharmacists. These are already evident and perhaps we are too late, but I still hope that pharmacy will prove to be the Prince Charming who will rescue Cinderella (pharmacology) and that such a marriage will lead to the appropriate and safe use of drugs by all.

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# BASICS OF THE CLINICAL COMPONENT OF PHARMACY EDUCATION

Presiding:

Jere E. Goyan, Ph.D.
Dean, School of Pharmacy
University of California

# TEACHING CLINICAL PHARMACY IN AN ACUTE CARE SETTING

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It is the purpose of this paper to describe the clinical activities of pharmacists and students in an acute care setting. However, it is helpful to review the elements of a successful practice and teaching environment before these activities are discussed.

To have major impact on the day-to-day drug therapy of individual patients the pharmacist must be easily accessible as a resource person to patients and health professionals; this does not mean easily accessible by telephone. A drug information pharmacist tucked in a corner of the library is soon forgotten and a unit-dose or parenteral-solution pharmacist who is "centrally" located in the basement of the hospital becomes a voice on the telephone harassing nurses and physicians unless there is daily personal interaction with a pharmacist on the ward. Also, the pharmacist must have ready access to patient records, the patient, and health professionals to provide the services she/he has the knowledge to provide. Some programs introduce pharmacists on the wards by placing them in decentralized unit dose areas; others establish clinical pharmacy offices on the wards which are as close to patient care related activities as possible. In any case, the clinical faculty at the University of California insist on the presence of a pharmacist on all wards where students take their required inpatient clerkships. The pharmacy practitioner, whom we call a preceptor, serves as a role model and teacher for the students, and ensures the quality of their patient care related experiences and contributions.

Prior to participation in formal rounds, we encourage students to prepare themselves by becoming thoroughly familiar with each patient and to anticipate any drug related problems or questions which may arise. This is achieved through a variety of activities.

An effective patient medication history which is taken by the student should always be more complete than that of the nurse or physician. During this process the student is instructed to assess the patient's knowledge of drugs and the attitude toward them; to determine the nature and severity of any adverse drug reaction which the patient may have experienced; and to establish discrepancies between the patient's actual ingestion patterns and the prescribed regimen. Students are frequently able to document drug induced disease through this activity.

Monitoring is an activity which involves chart review and direct assessment of the patient. Through monitoring, the student identifies and anticipates drug related problems and evaluates the patient's response to current drug therapy. The student interprets the patient's signs, symptoms, and laboratory results to identify problems which may (1) require drug therapy; (2) influence drug selection or dosing; (3) be aggravated or induced by drug therapy; or (4) misdiagnosed as a result of drug therapy. She/he also assesses the patient to determine if there has been a therapeutic failure, therapeutic success, or adverse response to the medication. Finally, the student evaluates whether or not therapy is optimal with respect to efficacy, safety, drug product selection, and dosing.

Literature documentation and support for the student's conclusions and recommendations are achieved through consultation with a drug information service or through individual literature retrieval and evaluation. Up to twenty-five percent of a student's day may be spent in the library. Patient-specific *drug information* consults are self-generated through the monitoring process or are specifically requested by physicians and other health professionals. Then, when the student has completed these processes, she/he reviews the findings and recommendations with the preceptor.

Participation in *formal rounds* with physicians and nurses ensures communication between health team members and coordination of patient care related activities. It is a time when all members of the health team together discuss each patient under their care. And it is at this time that the student may influence drug therapy decisions as they are being made. Drug related problems which have been identified through medication history and monitoring activities are brought to the attention of the team for discussion, and drug information consults are provided. It is important to emphasize that similar interprofessional interactions occur throughout the day and are not limited to formal rounds.

*In service education* for nurses and other health professionals is another activity in which students are encouraged to participate. As a rule, nurses receive minimal instruction in pharmacology. Because they see the patient more frequently than perhaps any other health professional in the acute care setting, they will be most likely the first to observe an adverse reaction to a drug. Instruction which emphasizes the safe, optimal administration of drugs and anticipation of adverse reactions can therefore have a strong positive impact on patient care.

*Patient education* with respect to drug therapy is another major in-house responsibility for the pharmacist. We encourage students to teach their patients something about medication each day during informal pharmacy rounds. We have found that it is much more effective to provide information in small increments than to educate the patient about a multiple number of medications just prior to discharge. The goal of this process is to improve compliance by enabling the patient to understand the influence which medications will have on his or her health.

As clinical pharmacy becomes established as a profession, the clinical pharmacist takes on more direct responsibility for patient care. As a result, the spectrum of role models which a student experiences and observes expands each year. For several years, pharmacists have been active members of the cardiac arrest team; others are beginning to assume major responsibility for the drug therapy of specific medical problems. For example, a pharmacist specializing in emergency medicine assesses and cares for drug overdose patients; and physicians at some hospitals refer all patients who require anticoagulation care to the clinical pharmacists who prescribe and monitor the effects of heparin and warfarin. Clinical pharmacokineticists who interpret serum level data and make specific recommendations for dosing based on this interpretation are also in the process of becoming established in a small number of acute care settings.

It is evident that the hospital brings together many elements - patients, patient care records, multiple health professionals, and library facilities - which facilitate the establishment of a successful clinical pharmacy teaching program. In this setting the student is required to integrate and apply his didactic education to a practical situation and to communicate effectively this information to patients and health professioanls. Faculty are observing more confidence and assertive behavior in many of our students, I believe, as a result of such coursework. They are anxious to assume responsibility and to meet the challenge of expanding their roles. This is essential if we are to expect more widespread establishment of a practice which is more appropriately focused on the patient. I am optimistic that this dramatic change in emphasis in pharmacy education will ultimately bear the fruit of a more gratifying professional practice.

# CLINICAL PHARMACY SERVICES IN AMBULATORY CARE

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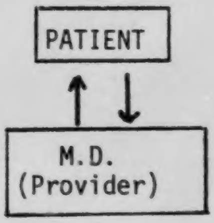
The goal of ambulatory clinical pharmacy services is identical with that of all pharmacy practice; to promote the rational utilization of pharmacotherapy. Achievement of this goal, however, must recognize differences imposed by an extended time-frame and a mobile patient. Most ambulatory patients have chronic diseases requiring long term therapy and monitoring. Also, ambulatory patients continue in their variable home environments and pharmacy intervention must recognize such backgrounds. Finally, decisions about hospitalization are ambulatory responsibilities.

The University of Maryland Division of Clinical Pharmacy provides operational ambulatory services at three sites, the Medical Primary Care Clinic, the Family Practice Clinic and the affiliated Veterans Administration Outpatient Department. The ambulatory clinical pharmacy services encompasses four basic roles; consultant, auditor, health care educator and provider.

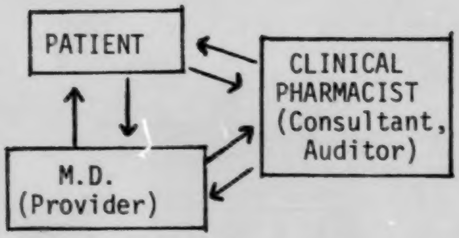
Depending on the particular health care system utilized, the interrelationships between clinical pharmacists, patients and health care providers range from simple to very complex, for example:

Model A -



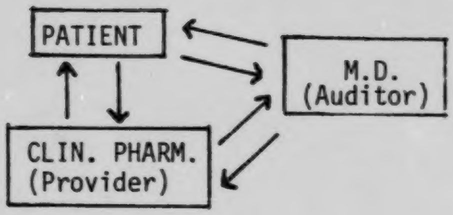
or

Model B -



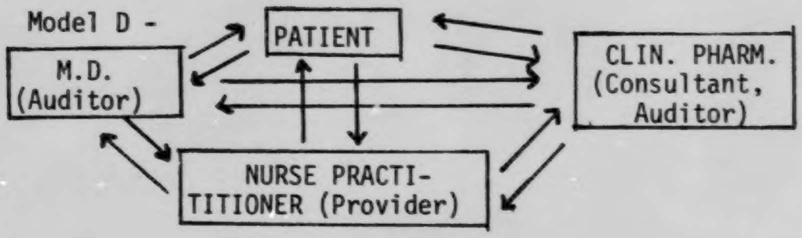
or

Model C -



or

Model D -


PATIENT
M.D. (Auditor)
CLIN. PHARM. (Consultant, Auditor)
NURSE PRACTITIONER (Provider)

The University of Maryland Hospital and Veterans Administration Hospital use Models B, C, and D with emphasis on Model D.

The team approach to the delivery of primary health care is the basic philosophy promulgated at these institutions in the belief that each discipline has an important background and knowledge base to offer to patient care; the physician contributes his diagnostic and management skills, the nurse practitioner offers psychosocial knowledge and patient care skills and the clinical pharmacy practitioner provides knowledge and skills in the use of pharmacotherapy.

I. Consultant Role

The objective of this role is to serve as a drug information specialist guiding health care practitioners and patients in appropriate use of therapeutic agents. The clinical pharmacy practitioner is often consulted when therapeutic problems or issues are recognized such as: (1) identification of the therapeutic objective; (2) institution and identification of the most appropriate therapeutic intervention; (3) identification of patient parameters for monitoring pharmacologic effect or toxicity; (4) recognition of patient noncompliance and/or improvement of compliance to therapeutic regimens; (5) determination of drug interactions or drug interference with laboratory tests; and (6) recognition of adverse drug effects with specific and corrective recommendations for treatment.

At the time of consultation, the clinical pharmacy practitioner at the University of Maryland collects the appropriate medical and pharmacy data base; approximately one-third of the time this involves eliciting the history, physical and laboratory findings directly from the patient. After collaboration with the provider and collection of all data, the clinical pharmacy practitioner documents in the medical record, using the problem oriented format, an assessment pertaining to the problem defined and a plan to obviate the therapeutic dilemma or issue, i.e. adjust the pharmacotherapy, educate patient and/or provider, list the data base parameters to monitor, etcetera.

## II. Auditor Role

An audit is defined as "an official examination and verification of accounts and records." A clinical pharmacy audit is an examination and verification of medical records for documentation of rational pharmacotherapy. The audits are performed by either of two well-known mechanisms, implicit and explicit systems.

An implicit audit is performed by using current therapeutic standards and applying them to cases identified by recency and/or poor therapy. This type of audit is usually done on a face-to-face basis with the clinical pharmacy practitioner sitting down with the provider or group of providers at the end of the clinic day in an audit session using a case conference format and discussing the pertinent therapeutic concepts from each situation with the solution(s) as illustrated by the day's work. Typical problems that are raised during an audit session include: (1) minimal criteria to be considered in prescribing a specific therapeutic agent; (2) therapeutic endpoints of specific modalities and how to monitor them; (3) clinically significant side effects or toxicities of prescribed drugs; (4) dosing intervals of agents and the relationship to the pharmacokinetics; (5) patient education or its absence. These audits have positively influenced physician prescribing habits and quality of health care. This is recognized by the impression that the medical records display more therapeutic information, patients are receiving more drug education and physician awareness to drug toxicities, side effects and therapeutic endpoints are more apparent. Since the implicit audit deals with common therapeutic problems encountered during daily practice, its relevance to providers is obvious. An additional benefit of this audit system has been a related increase in the number of clinical pharmacy consultations.

The second audit mechanism, the explicit audit, utilizes predetermined written criteria developed to study drug utilization and quality of medical care. At the University of Maryland Hospital and its affiliate, Veterans Administration Hospital, an audit committee develops such audit criteria. Members of the committee include three internists, two clinical pharmacists, and one nurse practitioner and two patient care evaluation assistants. The committee is chaired by a clinical pharmacist and the data is gathered from the medical records by the patient care evaluation assistants under the instruction and guidance of the committee and chairman. Table 1 displays some of the audits performed to date with results obtained, recommendations made and changes seen in clinical practice. It should be pointed out that the explicit audit system discovers trends in medical care and often identifies the cause(s) and suggested recommendations are made to rectify the problem. Note also that results are given to the appropriate educational system in all cases. In our scheme at Maryland, also note that clinical pharmacy input is significant, i.e. chairing the committee, disseminating the results, participating in the educational endeavors through the implicit audit system and in several cases devising protocols for management of specific problems. Currently, there are three different hypertensive clinics, two anticoagulant clinics and a medical primary care clinic operating with protocols devised by the clinical pharmacy division.

## III. Educator Role

Dissemination of drug information is intrinsic to all clinical pharmacy services. The education role referred to here, however, is involvement in the formalized training of undergraduate and graduate programs in health professional disciplines. The following examples are brief descriptions of current structured programs which are part of ambulatory clinical pharmacy instruction at the University of Maryland Medical Primary Care Clinic (Clinical pharmacy practice at the Family Medicine Clinic and the Veterans Administration outpatient clinics are roughly similar.). The pharmacotherapeutics portion of the Nurse Practitioner Program is taught by a clinical pharmacist and includes approximately thirty hours of didactic lecture presentations and ten to fifteen hours of case discussions per semester, the latter involving interdisciplinary personnel. Senior medical students rotate during a six-week period in the Primary Care Medical Clinic and during that time clinical pharmacy conferences are held for three hours per week. The sessions use seminar teaching techniques and discussions center around common outpatient therapeutic issues. Residents from the Department of Medicine of the University of Maryland Hospital also rotate in the Medical Primary Care Clinic and one hour per week is spent discussing pertinent medical and therapeutic issues. Fifth-year pharmacy students and Pharm.D. students rotate through the clinic in clinical clerkships for 4-week rotations, 40 hours per week. The students, with the guidance of the clinical pharmacy instructor, follow and monitor patients with therapeutic problems, perform consults, assist in therapeutic audits, participate in seminars, observe services provided by all health professionals, provide patient education and learn a practical approach to rational drug therapy. The advantages of teaching in clinical areas are obviously those of relevance and immediacy.

## IV. Provider Role

The purpose of this role is to deliver health care. Because clinical pharmacy practitioners have advanced training in pathophysiology, clinical therapeutics and pharmacokinetics, health education as well as practical clinical clerkships, they have the capability of rendering health care under the preceptorship of a physician once physical diagnostic skills are mastered. At the University of Maryland physical assessment skills are attained via a one-year course in physical diagnosis through the School of Medicine. Follow-up skills are attained under close physician supervision in a data base clinic where the clinical pharmacist obtains the complete medical data base from new patients. After completion of the course, Data Base Clinic and successful completion of a practical skills test given by an internist, the pharmacy practitioner proceeds to work-up and follow selected patients. The potential of this role is obvious in areas of low physician census. Additionally, problems needing multiple or complex therapeutic modalities are ideally followed and managed by the clinical pharmacist thus assuring safe and rational patient care. Such problems include hypertension, diabetes mellitus, most chronic diseases and anticoagulant therapy. Knowledge in physical assessment also improves the clinical pharmacist's capability and practicability in dissemination of drug information as a therapeutic auditor and consultant. Finally, such skills will also increase his participation and credibility in patient care. For example, he will be better able to coordinate, detect and quantify adverse drug reactions.

To conclude, this paper has attempted in a general manner to provide an overview perspective of ambulatory clinical pharmacy services as practiced at the University of Maryland. Other institutions will likely have different formats of patient/provider interactions; the roles presented are basic, however, and only the emphasis will be different. Not to be overlooked, is the importance of clinical pharmacy services being integrated into educational and research systems whenever possible.

## TABLE 1
## EXAMPLES OF EXPLICIT AUDITS

| Audit Topic | Purpose | Results | Recommendations and Conclusions | Changes Made in Clinic Practice |
|---|---|---|---|---|
| Hypertension | To determine the effectiveness of antihypertensive therapy. | 1. 21% of hypertensive patients were controlled.<br>2. 5% of patients were not given reappointments. | 1. Specify predetermined therapeutic goals<br>2. Justify deviations from therapeutic goals.<br>3. Provide continuous practitioner education regarding therapy.<br>4. Develop a mechanism to double check reappointment procedures. | 1. Algorithmic protocol for treatment devised by clinical pharmacy.<br>2. Results given to all providers, administrators, and auditors.<br>3. Conferences were developed by internists and clinical pharmacy to discuss therapy.<br>4. Reaudit currently in progress. |
| Digitalis Utilization | To determine if digitalis glycosides were given to patients for generally acceptable indications. | 1. 96% of patients had acceptable process. | 1. Continue to emphasize acceptable cardiac indications for initiation of digitalis especially in the educational process. | 1. Results were given to providers, administrators, auditors and Division of Cardiology.<br>2. Reaudit in future. |
| Cost of a Cold | To estimate the average cost to treat a cold in a non-complicated patient. | 1. Average Lab cost per patient-$3.18<br>2. Average wholesale drug cost per patient - $1.62<br>3. Average cost per patient excluding clinic fee - $4.80 | 1. Cost of diagnosis and treatment for simple cold is excessive.<br>2. Increase vigor of audit teaching programs.<br>3. Limit drug detailmen in clinic areas. | 1. Results given to providers, administrators, and auditors<br>2. Intensity of implicit audit programs increased.<br>3. Procedure for detailmen access to clinical areas reviewed by the administrator.<br>4. Reaudit in future. |
| Smoking and Alcohol Intervention | To determine if an attempt to modify smoking and alcohol use in patients with Lung and Liver disease respectively was performed. | 1. 25% of medical records did not recommend any form in intervention. | 1. Providers need further education in dealing with known risk factors, smoking and alcohol use.<br>2. Provide intervention training. | 1. Results were given to providers, administrators and auditors.<br>2. Dept. of Social & Preventive Medicine is currently setting up an intervention program.<br>3. Reaudit in future. |

# PATIENT INTERVIEW

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The purpose of an interview is to gather information. The information obtained from the patient may be used to define the patient's problem, provide data for decision making and form the basis for helping the patient. The pharmacist must interview when he directs patients toward appropriate health care, suggests a non-prescription drug, obtains a medication history, monitors the outcome of therapy or provides patient education and follow up. In each of the above activities, there is the necessity to gather data, define problems, make decisions, and communicate helpful information to the patient or a health professional.

It is useful to start the interview with the realization that each patient has a unique perception of his state of health. This perception is a function of many interacting factors: 1) the patient's theories and beliefs about disease; 2) the patient's community and cultural background; 3) the degree of distortion that illness produces in a patient's behavior, his family life, his job, and his bodily processes; and 4) the patient's own goals, priorities and value systems. Dr. Fuller has defined health as a value judgement made by the patient that applies to the immediate present and is subject to change with the passing of time. It follows that the information gathered from a patient during the interview may not be meaningful or relevant unless it is considered in the context of the patient's perception of health.

The interview is initiated by the following actions of the interviewer:

1) the patient is greeted in a courteous manner.
2) the interviewer identifies and introduces himself.
3) the patient is told the reason for the interview and is given an approximate time frame for the interview.
4) the interviewer elicits the patient's approval to proceed.
5) the comfort of the patient is considered.
6) the interviewer establishes a physical or psychological setting of privacy. Patients do not wish audiences when they are discussing their problems.

The interviewer should have an open natural manner that demonstrates empathy for the patient. The interviewer should establish effective eye contact with the patient and give his full attention to the patient's verbal and non-verbal responses. Questions should be short and compatible with the patient's vocabulary and level of understanding. The interviewer must recognize that his questions have the potential to interrupt, confuse, and bias the patient's response.

The interviewer may choose from several styles to conduct the interview. One style is the open ended question format in which the patient is encouraged to speak with a minimum of guidance or input from the interviewer. An example of this format would be the following question: "Can you tell me about your experience with drugs?" The open ended format is a very patient centered style that allows the patient to define his problems, his observations and his questions in his own manner without the potential bias introduced by questions from the interviewer. Because the burden of communication is placed with the patient, he is encouraged to actively participate in defining and solving his problems. It has been suggested that active participation by the patient in defining problems and decision making will increase the patient's compliance with therapy.

A very different style of interview is the closed ended question format which is interrogative in nature and interviewer centered. The interviewer directs the interview by asking questions that give the patient a minimum of freedom of response. An example of this type of format would be the following question: "Did you abuse drugs?" The major disadvantage of this style is the potential for interviewer bias introduction and the potential for ignoring the patient's concerns and questions. The advantage of this format is that it lends itself to a comprehensive and systematic gathering of data through multiple specific questions. For example, a comprehensive drug history may be obtained by asking multiple questions about drugs in each pharmacological class or by asking questions based on drugs used in a specific organ system such as respiratory, cardiovascular, etc.

When the interview is about to be concluded, the interviewer may wish to verbally summarize the important points covered in the interview. This summary is a check for understanding between patient and interviewer. The interviewer often concludes the interview with the following questions: "Is there anything else I should know?" and "Do you have any questions for me?" This allows the patient the chance to fill in information that is missing or voice concerns. The patient should be thanked and told if he will have further contact with the interviewer.

* * * * *

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# PATIENT MONITORING

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Patient monitoring is a task that all of us do every day. The task may not be as complete as I will describe later, but it does include one very important aspect of monitoring - that is the patient's subjective feelings. Of course, what I am talking about is the single greeting. "Hello, how are you today?"

Inpatient monitoring, in this day of mechanization, is usually interpreted to mean laboratory tests, x-rays, cardiograms, etc. But really, it includes all of these findings plus a physical exam and oral interview of the patient.

The pharmacist may not be able to interpret these reports directly but he must be capable of understanding the assessment by a specialist.

Each patient has the potential to produce great quantities of data that must be interpreted and organized into a proper monitoring profile. The correct profile for each patient is influenced by the patient's disease state(s), modes of treatment, and the available resources. The question then becomes: Which test and how often?

Example: Blood sugar determinations are more critical and done more frequently in the diabetic patient receiving insulin than in the mentally ill patient receiving phenothiazines.

Patient monitoring requires that you know at what point between life and death the patient is currently at. A baseline or starting point, must be established. This means a complete understanding of the patient's prior medical history and his present disease process or processes.

This review includes past medical history, the reason he came to the hospital, current medical problems, review of body systems, and drug history.

You have now established your starting point for monitoring and, with a knowledge of disease states, have some idea of its course if untreated.

Once treatment is decided on, each drug or treatment must be evaluated as to why it is given, what is the therapeutic objective, and what can it do, both good and bad. The pharmacist must realize that all forms of treatment, not only drugs, influence the disease process and monitoring criteria. Example: mechanical ventilation alters arterial oxygen concentrations.

The monitoring criteria are tailored to meet the needs of the patient's disease state, his starting point, and drug therapy. There criteria will indicate therapeutic progress, success, or failure, plus alert the medical team to complications of the disease state or side effects of the treatment.

Let us briefly look at the components of monitoring. The Clinical Laboratory, which measures the concentrations of substances in the body, has grown considerably in the last twenty years. Although most of the tests are accurate and reproducible, their interpretation and application to the patient is much less concise.

The interpretation of these results must be tempered by the reality that we are not always sure what the normal value for a test should be and how great a change from normal is of significance. The tests are subject to change by treatment, disease states, age, collection procedures, time of day, and sex to name but a few variables. Because these tests are subject to many variables, they must be interpreted with all other information. The over-riding question of each test result is, "Does it fit all of the other findings in this patient?"

This sounds complex and it can be at times, but my main point is that these numbers are not perfect or absolute, and are only one piece of the puzzle in patient evaluation and monitoring.

There are many other tests done outside the clinical laboratory. These include such procedures as x-rays, radioisotope scans, computer axial tomography, and electrocardiograms (just to name a few). I have not clarified in my own mind how involved the pharmacist should be in interpretation of the original work, but he must be able to understand the interpretations of others.

Example: You might not be able to "see" an infiltrate on a chest x-ray, but once the radiologist sees it and says so, the pharmacist should be able to use this information in monitoring the patient.

Clinical assessment is a combination of objective physical findings and subjective feelings of the patient. This is the "art" of medicine. It is still an extremely important part of medicine in spite of all of our sophisticated gadgetry. Clinical assessment is usually the final answer when you have two conflicting pieces of mechanized data.

The emphasis in the foregoing discussion was patient monitoring in the institutional setting. This can also apply to the outpatient setting. The outpatient area usually require greater reliance on clinical assessment.

The pharmacist selling over-the-counter preparations can perform some of this by asking a few questions. The patient who asks for a cough suppressant would be asked how long he has had this cough. If it has been longer than a month you might encourage him to see a physician rather than self-medicate.

Chronic disease monitoring programs are being developed in this country. They require that the pharmacist have some physical assessment skills to monitor the patient's progress.

Patient monitoring can become very complex and involves a great deal of data that must be recorded and analyzed. The patient's medical chart is the source of a great deal of this data, but may not be readily available or organized correctly. Some pharmacists have devised charts and protocols for certain specialized areas. Total parenteral nutrition is such an area.

These protocols serve as memory aids, data gatherers, and excellent teaching tools. The computer will hopefully be able to replace the pen and pencil as a storer and displayer of this kind of information.

The computer will not replace the human brain as the final arbiter and interpretor of the patient's condition.

Patient monitoring is a combination of both the art and science of medicine. There are intangibles of intuition, common sense, and experience that cannot be taught from books. Because of this the student must learn about patient monitoring while actively involved in patient care. There is no substitute.

In conclusion, I would like to re-state these important points:

1. The patient's monitoring profile is influenced by both his disease state and treatment.
2. Patient monitoring is a combination of mechanized data such as clinical labs and other tests, plus clinical assessment. No single test is absolute.
3. Because medicine is an art, it must be learned in the clinical setting.

# PATIENT EDUCATION

Yolanda Durley Pharm.D., Assistant Professor, College of Pharmacy and Allied Health Programs, Wayne State University

I'm known as the clinical pharmacist at Metropolitan Hospital in Detroit, Michigan. Metropolitan Hospital is a prototype Health Maintanence Organization with a total enrollment of 82,000 members.

Aside from the previously mentioned clinical pharmacy activities such as ambulatory counseling and chronic disease monitoring, for the past year I've served as coordinator for two patient education classes, Diabetes Mellitus and Hypertension. I'd like to share with you this interesting experience.

First, let's review the goals and objectives for patient education.

A. Goals for patient education

Narrows the gap between the health provider (such as the physician) and the patient.
Places the burden of chronic disease control upon the shoulders of the patient.
Enables the patient to function as independently as possible.

Sub-goals of the clinical pharmacist for patient education

Minimize medication errors.
Increase compliance (Must help the patient and his/her family integrate necessary therapy into the pattern of daily living.).

B. Behavior objectives for patient education

The patient should be able to discuss in his/her own words the physiology, epidemiology, control and complications of his/her disease state.

Sub-objectives of the clinical pharmacist for patient education

The patient should be able to list all of his medications, their corresponding side effects, and indicate which effect should be reported to the physician.
The patient should be able to correctly state the purpose and directions for use for each medication.
The patient should be able to list 5 non-prescription preparations which should be avoided.

There are two principle ways of educating the patient. Individually on a one to one basis. Each interaction between the physician-patient, nurse-patient, clinical pharamcist-patient (such as medication consultations) and dietitian-patient can be considered an educating process for the patient. This method tends to be unorganized and fragmented, however certain patients respond favorably, approximately twenty-five percent. The second method, group sessions, which is a highly integrated multidisciplinary patient education service.

I will now discuss how we organized and currently conduct our hypertension classes at Metropolitan Hositpal. A patient education committee was formed representing nursing, dietitary, social services, clinical pharmacy, administration and medicine. This committee developed the goals and objectives of patient education for our hospital and a budget. A subcommittee for hypertension developed the sub-goals and sub-objectives for each discipline. Determined the structure of the class, such as the number of sessions, the time and length of each session, audiovisual equipment, and handouts. After selecting a pre-class questionnaire, history, referral and evaluation form, we were ready for classes. (preparation time, approximately six months)

The patient education committee presented our proposal to the medical staff (80 physicians). I cannot emphasize the importance of seeking approval and cooperation of the medical staff.

Hypertension Class is presented monthly, each class consists of four weekly sessions, ninety minutes per session, Time 4-5:30 p.m. on Thursday afternoons. We use a series of booklets developed by Dr. Zweifler, director of the Hypertension Clinic at the University of Michigan and published via a grant, by the Michigan Association for Regional Medical Programs.

Session
1. Pre-class questionnaire and history presentation by the physician, explaining the physiology and epidenmiology of hypertension.
2. A film is shown which reviews the physiology, control and complications of high blood pressure.
   Presentation by the clinical pharmacist, medications.
3. Presentation by the dietition, diet.
4. Presentation by the nurse, activity and the social worker, stress.
   Evaluation form.

The patient is weighed at the beginning of each weekly class and the blood pressure is measured at the end of each class. We consider the optimal class size to be 10-15 patients.

## METROPOLITAN HOSPITAL AND HEALTH CENTERS

### Evaluation of Patient Education Classes

☐ Hypertension Class ☐ Diabetic Class

You may check more than one response to each question:

Was the content of the classes:

- ☐ interesting
- ☐ informative
- ☐ relevant
- ☐ repetitious
- ☐ inappropriate
- ☐ dull
- Other ____________________

On the whole, would you rate the class as:

- ☐ poor
- ☐ fair
- ☐ excellent
- Other ____________________

The discussion leaders were:

- ☐ well-prepared
- ☐ easy to understand
- ☐ enthusiastic
- ☐ not prepared
- ☐ hard to understand
- Other ____________________

If you could make some changes in the classes, what would you change?

How do you think you will benefit from the classes?

## HISTORY

Patient's Name: ______________________

Med. Rec. No.: ______________________

Age: ________ Sex: ________

Marital Status: M S W D

Living Situation (alone, w/family, etc.):

______________________________________

Oneset of disease/condition: __________

Family History of Disease: __________

Medications - Past: ______________

______________

Current: ______________

______________

Diet - Past: ______________

______________

Current: ______________

______________

Alcohol/Drug Dependencies: __________

______________________________________

Smoking: ______________________

Weight: ______________________

Exercise: ______________________

Blood Pressure: ______________________

Other Chronic Diseases: __________

______________________________________

Hospitalizations: ______________

______________________________________

Compliance with M.D. visits: __________

______________________________________

Class 1 - Date: __________

Content: ______________________

______________________________________

Outcome Measures: ______________

______________________________________

______________________________________

Comments: ______________________

______________________________________

______________________________________

Class II - Date: __________

Content: ______________________

______________________________________

Outcome Measures: ______________

______________________________________

______________________________________

Comments: ______________________

______________________________________

Class III - Date: __________

Content: ______________________

______________________________________

Outcome Measures: ______________

______________________________________

______________________________________

Comments: ______________________

______________________________________

______________________________________

Class IV - Date: __________

Content: ______________________

______________________________________

Outcome Measures: ______________

______________________________________

______________________________________

Comments: ______________________

______________________________________

______________________________________

Class V - Date: __________

Content: ______________________

______________________________________

Outcome Measures: ______________

______________________________________

______________________________________

Comments: ______________________

______________________________________

______________________________________

# HYPERTENSION PRE-CLASS QUESTIONNAIRE

NAME: ______________________________ Date: ______________

1. What would you most like to learn in this class? ______________

______________________________________________

______________________________________________

______________________________________________

2. When did you first find out about your high blood pressure? ______________

3. Did you have any signs or symptoms of high blood pressure? ___ Yes ___ No
If yes, what symptoms did you have? ______________

______________________________________________

4. What instructions has your doctor given you concerning your high blood pressure? (Please check one or more answers.)

____ to follow a low salt diet
____ to lose weight
____ to follow a low fat (cholesterol) diet
____ to take pills daily
____ to stop smoking
____ to get more exercise
____ to stop worrying so much
____ to "take it easy"
____ None of the above

5. When did you last visit your doctor? ______________

When is your next appointment? ______________

WHEN ANSWERING THE FOLLOWING QUESTIONS, PLEASE CIRCLE ALL OF THE ANSWERS THAT YOU FEEL ARE RIGHT. THERE MAY BE MORE THAN ONE ANSWER TO EACH QUESTION.

6. High blood pressure is a condition that

a. is caused by worrying too much
b. is caused by eating too much
c. usually has no known cause

7. A person has high blood pressure when his/her blood pressure is

a. 120/80
b. 100/50
c. 200/105

8. Hypertension, another name for high blood pressure, is a condition that

a. will go away if the person gets a lot of rest
b. can be cured with medicine
c. will never go away but can be controlled with medicine

9. If a person doesn't get treatment for high blood pressure

   a. s/he may feel fine and be in no danger
   b. s/he may feel fine but has a much greater risk of having a heart attack
   c. s/he will feel weak and dizzy all of the time

10. Medicines for high blood pressure should be taken

    a. only when a person feels sick
    b. even when a person feels good
    c. even if the medicine makes the person feel worse

11. Regular exercise can

    a. cure hypertension
    b. help control high blood pressure
    c. increase the risk of heart attacks

12. A person with hypertension

    a. should get regular exercise but not participate in rough sports
    b. can do any sport or activity if his/her blood pressure is controlled
    c. should avoid all sports and vigorous exercise

13. A person with high blood pressure who is often angry and frustrated with his/her boss,

    a. should quit his/her job
    b. should learn to express his/her anger in a better way
    c. should learn to keep "cool"
    d. should learn to keep anger inside of him/her

14. When a person has high blood pressure, it is often recommended that

    a. s/he eats lots of salty foods
    b. s/he stops adding salt to his/her food at the table
    c. s/he stops eating all salty foods

15. Foods that have a lot of salt (sodium) are

    a. bananas, oranges, apples
    b. cheeses, smoked meats, olives
    c. nuts, pretzels, potata chips

16. High blood pressure is one factor that increases the risk of heart attacks. Other risk factors are:

    a. smoking
    b. high level of fats (cholesterol) in the blood
    c. being overweight
    d. drinking
    e. working too hard
    f. bad blood
    g. not getting enough exercise

17. A diuretic, or water pill

    a. helps the body get rid of extra water
    b. causes the body to hold more water
    c. causes the person to drink more water

18. When a person with high blood pressure gets a cold or cough, s/he should

a. use any non-prescription cold or cough medicine
b. ask her/his doctor or pharmacist which medicine to take
c. not use any cold or cough medicine

19. If a person gets dizzy often s/he should

a. keep taking blood pressure pills and report her/his symptoms to the doctor
b. double the dose of his/her blood pressure pills
c. stop taking her/his blood pressure pills and call the doctor
d. ignore the dizziness and keep taking the pills

20. A person with high blood pressure should see her/his doctor

a. about once a year
b. only when s/he is feeling sick
c. only when his/her blood pressure pills run out
d. as often as recommended by the doctor

21. Smoking

a. does not affect blood pressure
b. makes it more difficult to control high blood pressure
c. increases the risk of a heart attack or stroke

22. If a person has high cholesterol (fat) in the blood, some foods that s/he should limit are:

a. fatty meats
b. cheese
c. eggs
d. shrimp
e. nuts
f. fresh vegetables
g. sweets
h. bread

23. Give the name or color of all of the medications you are now taking and tell what times during the day you take your medications

What kind? What time taken?
________________________________________
________________________________________
________________________________________
________________________________________

24. What non-prescription medicines do you usually take

for a cold? ______________________________

for a cough? ______________________________

for stomach trouble? __________________________

for constipation? ___________________________

for sleep at night? __________________________

for pain? ________________________________

# DRUG INFORMATION - A BASIC OF THE CLINICAL COMPONENT OF PHARMACY EDUCATION

Ann B. Amerson, Pharm.D., Assistant Professor, College of Pharmacy, University of Kentucky

Drug information can be simple or complex. It can imply a statement written in a book or the analysis, synthesis and evaluation of extensive information from numerous sources; or it may describe a role which the pharmacist fulfills whether in the community pharmacy, the hospital or a drug information center. Thus, the term drug information can be used in a number of ways. For the purposes of this discussion, the term drug information refers to efficient and effective use of the literature.

The literature may be divided into three components: primary, secondary and reference literature. The term, primary literature, refers to articles published in journals which deal with original clinical research or documentation. Secondary literature is comprised of various tools such as abstracting services (e.g. Iowa Drug Information Service, deHaen Abstracting Services) and indexes (e.g. Index Medicus) which allow retrieval of specifically needed articles from the primary literature. References are a group of texts and sources which have distilled well documented information into a compact form for quick reference. Some overlap among the three components may exist but these general designations can be made.

As the practice of pharmacy evolves toward a greater clinical emphasis, it is essential that every pharmacist acquire some level of expertise and knowledge of the different components of the literature. The pharmacist currently in practice in the United States can and should provide information on drugs to meet various patient and health professional needs. One of the instruments needed to do this effectively and efficiently is the ability to use the literature. As the practice changes, greater emphasis on this ability is expected.[1]

Basic knowledge should include information and actual use of all three components of the literature. The reference component is probably the most important since these sources are more readily available to the pharmacist in the majority of our current practice settings. Several types of references are emphasized as illustrated in Table I which gives representative examples. The primary and secondary literature components are discussed hoping, that as our practice settings evolve, many more pharmacists will find the opportunity and need to utilize such sources. Even if this does not occur immediately, the pharmacist should know the existence and capability of such sources as Index Medicus, deHaen Drugs in Use, and International Pharmaceutical Abstracts. When the need arises, a facility which has these sources, such as a drug information center, can be contacted. These centers are staffed generally with pharmacists who have received additional education in all components of the literature with a much greater emphasis being placed on development of a high level of competence.

Drug information or as earlier defined, efficient, effective, use of the literature, involves a number of capabilities such as being able to retrieve, to utilize and to communicate information. Utilization further involves such processes as selection and evaluation. It must be kept in mind that different levels of competency for each of the skills can be achieved. Every pharmacist should be able to demonstrate a defined level of competency in the use of the reference literature. The pharmacist who enters an advanced degree program and plans to practice in a hospital clinical environment or in a drug information center generally needs a higher level of competence with primary and secondary literature than the pharmacist in the more traditional setting. The nature of the drug information problems encountered in these environments are somewhat different.

The educational background of the pharmacist must provide the opportunity to acquire the knowledge base described and to demonstrate a defined level of competence before actually entering practice. In order to accomplish this, the literature should be introduced early in the student's education and built upon in subsequent courses. Drug information centers sometimes are used as a resource for teaching students about the literature. Such a resource is not essential and a reasonably good library with acquisition of the appropriate literature can provide the necessary tools. The student can be given structured exposure to the literature by use of exercises (assignments) with questions designed to emphasize certain characteristics or advantages of a reference or source. Other assignments of a comparative nature can be employed which allow the student to compare the information on a given drug obtained from several sources. In this fashion, the basic knowledge of the different literature components can be achieved before clinical experience in the curriculum. Incorporating use of the literature into the student's clinical course work or experience in a systematic way can illustrate how the literature can be a valuable asset in practice. In addition, the opportunity exists to emphasize and to demonstrate selection of relevant information from the literature and the application of judgements about that information in regard to specific patient problems. Communication skills can be emphasized.

Several benefits result from being able to effectively use the literature. If the pharmacy student is introduced to some of the basics of the literature early in the educational process, the literature then becomes a tool to enhance the traditional component of education as well as the clinical component. By developing the capability of efficient, effective use of the literature, the student, once a practitioner, can select the drug information sources needed for a particular practice setting and develop a role as a provider of drug information. The literature, in addition, provides the opportunity for individualized continuing education and the capability to effectively use the literature hopefully stimulates a desire to keep informed of current developments. Drug information, as defined in this discussion, is an important basic ingredient of the education of a pharmacist.

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# THE INTEGRATION OF CLINICAL PHARMACY INSTRUCTION

David Burkholder, M.S., Pharm.D., Professor and Assistant Dean, School of Pharmacy, University of Missouri-Kansas City

From the previous presentations made this afternoon, it must be apparent to each of you that clinical pharmacy instruction is provided in several modes and environments. Clinical education is indeed complex when we view its processes within the context of pharmaceutical education specifically and health science education more generally.

If we were able to construct an ideal and very complete, model for clinical pharmacy within the framework of pharmaceutical education and even larger framework of health science education, we would find numerous points of integration with other types of instruction, faculty and elements of patient care. The composite model would be three-dimensional with numerous interfacings or inter-digitations and with lines drawn in many directions and at all possible angles. Such a model would probably be no less complex than that depicting the chemical structure for DNA. Because there are so many different models for clinical pharmacy in existence, it may be preferrable not to describe in detail any particular one, but rather, to discuss more generally their integrative relations with curriculum, faculty, environments, instruction and evaluation. With these reference points in mind, let us consider the various ways for integrating clinical pharmacy instruction to achieve our particular educational goals and objectives.

## 1. Curriculum

The pharmacy curriculum should be designed to accommodate clinical instruction in a series of progressive steps beginning very early in the student's professional education. Each step or level of instruction should have its own identifiable goals and objectives which are cumulative throughout the curriculum. The sum total of these goals and objectives should be based on all those competencies expected for clinical practice at the conclusion of the student's professional education. In this manner, the knowledge and skills acquired gradually build in their sophistication and application, moving in successive steps from mere exposure, to directed and more personal involvement, and finally to learning experiences which allow for the exercise of some independent judgment. This represents a longitudinal design for clinical instruction which builds progressively in terms of acquired knowledge and skills and also in the time given for clinical instruction within the curriculum, i.e. as an expanding wedge within the curriculum. At the upper levels of instruction, sufficient time must be allowed for following patients on a daily basis and this may necessitate an open block of several weeks within the curriculum where no other courses of instruction are provided.

Throughout this continuum of clinical instruction, there must be close alignment and integration of subject matter with that being offered concurrently in other courses. At each step throughout the curriculum the student should see increasing use being made of the basic knowledge acquired in previous and concurrent didactic courses. This requires the utmost care in planning for the integration of pharmaceutical and biomedical knowledge with the clinical "laboratory" instruction being given. One may think of this as the other dimension to curricular integration depending on how you lay the curriculum out, i.e. in vertical or horizontal steps and levels. In either case, the information provided in concurrent courses is integrated within the clinical instruction given at the same step or level of the curriculum.

To assure better integration of clinical instruction throughout the pharmacy curriculum, it would be even more ideal if the same clinical instructors were providing the same group or class of students their clinical instruction in progressive steps. In this manner, the clinical instructors would become more aware of all pharmacy instruction at each step and could follow the progress of their individual students just as they follow the care of patients.

## 2. Faculty

A basic feature common to all clinical instructors is their simultaneous development of two professional roles: one as a pharmacy practitioner and the other as a teacher. This is implicit in their ability to serve as exemplary "role models" in practice and their acceptance of responsibility to teach students within their practice setting. This duality of purpose is mutually supportive to both roles. As the level of practice increases, so generally does the capability to offer instruction, much the same as research accomplishments enable the scientist to provide more information to his graduate students.

It also requires that the clinician integrate his practice abilities with the most effective teaching methods available, often in an extemporaneous and less structured manner than one sees in the classroom. This requires great adaptation in teaching. It means that the instructor must continually be alert to those learning experiences which "fit" the instructional goals and objectives and which meet the particular needs of individual students.

It must be emphasized that the level of clinical instruction provided can be no greater than the instructor's level of practice, and therefore, the expectations for what is taught should not exceed the role-model as described within a given practice setting. This is particularly important for the clinical instruction given at the upper, more advanced levels. The practitioner-educator must himself or herself be capable of integrating all the facts, skills and concepts of pharmacy with the more important facts, skills and concepts of medicine and patient care if he or she is to serve as an effective role model for students. This is a very large responsibility that extends from one of being a drug expert to one of being an expert in therapeutics. The full acceptance and utilization of the clinical pharmacist by his or her medicine colleagues is essential. The best indication of this may be the sharing of clinical pharmacy faculty through joint appointments as is the case in some programs. There are, as well, natural economies which result from the sharing of faculties.

Because of the high expectations held for clinical faculty members -- both as practitioners and teachers, there must be a lifetime of learning that goes on. The clinical instructor must always be both the teacher and the learner.

If this were not so, he or she would soon become obsolete as clinical practitioner, and consequently, as a clinical instructor. The great benefit they derive is one of a continuing education which is not just a fringe benefit but an expectation of everyday practice.

### 3. Environments

Learning environments may occur wherever patient care is being provided, but we would naturally select those sites which demonstrate a greater concern for the rational use of prescribed medication. The previous speakers have discussed in some detail some of the preferred sites for student instruction.

For any particular program of clinical instruction, there should be a suitable mix of learning environments which parallel all the contemporary systems for patient care delivery. These should begin with primary care settings such as one would find in selected community pharmacies wherein patient-medication records are reviewed and patient counselling occurs regularly. There might also be use made of community care clinics where medication problems may be identified with subsequent patient consultation or referral for medical evaluation as a follow-up procedure. Secondary patient care settings such as one would find in large group practice clinics and community hosiptals offer the student an opportunity to observe the use of a wide variety of drugs for diagnosing or treating all of the more common types if illness. The tertiary care centers are where the student can best observe the most advanced use of drugs in treating acutely ill patients requiring special care. These are often the large clinical teaching and research centers one finds in a health science center.

It is only natural that any school or college will utilize those clinical sites most accessible to faculty for role model development and student instruction. For some this has meant heavy reliance on primary care facilities within the community and for others exclusive use is made of a tertiary care center such as a university hospital. As a beginning this may be fine, but in neither case is this an optimal teaching situation for all students at all levels. It does not parallel the broad spectrum of patient care delivery systems in use today. Every effort should be made to accommodate students in all the contemporary settings of patient care in an integrated manner.

Most often students are first introduced to the primary care settings within the community. Here, the opportunity for student-patient interaction and communications is perhaps the greatest. At the more advanced levels of instruction, the secondary and tertiary care centers are utilized to demonstrate the patient care team concept where the pharmacist, as an integral member of the on-site team, has maximum opportunity for interprofessional communications regarding the safe and effective use of drugs.

A very central theme in all clinical teaching environments is the need for drug communications -- provided either for ambulatory patients or for other members of the patient care team. This should underscore the importance of how we communicate our information and therefore the need for courses in behavioral science and communication technology within the curriculum.

## 4. Instruction

The majority of clinical instruction is provided as supervised experiential learning, interspersed with frequent topic discussions and case reviews in small groups.

As mentioned earlier, it is important that each course of instruction or progressive step in the continuum of clinical instruction have its own stated goals and objectives. All instruction which is provided should attempt to achieve these goals and objectives in as consistent a manner as possible whereever the students are assigned for this purpose, which may be in multiple settings for students within the same class. To achieve this consistency of learning experience, which in itself is an important goal, requires that we "structure" the learning experience as much as possible. This can be accomplished more easily in clinical care settings where patients move through the system in a fairly consistent manner and pharmacist-patient encounters are somewhat predictable at certain times and places. The best example of this may be in a large clinic where semi-private stations are designed to accommodate patient counselling at the time home care prescriptions are being filled. This offers an excellent opportunity for student instruction utilizing patient-medication profiles and patient chart information in a well planned and structured manner. This type of structured teaching may be more suitable for early and intermediate levels of clinical instruction.

At the more advanced levels of clinical instruction, greater use is made of inpatient care settings within hospitals where clinical pharmacy role models are well established. Here the instruction may be less structured, more diverse and extemporaneous, but generally more advanced and sophisticated in content. It is like any science where one first learns all the basic rules and then through more advanced knowledge, one learns there are exceptions to almost every rule. At this more sophisticated level of learning, the student-faculty ratio must necessarily be very low, usually not exceeding four students for each clinical instructor.

It is at this more advanced level of instruction that we also see maximum use made of self-learning techniques. Much of the information must be derived by the student through selected readings, audio-visual materials, and drug information references which should be thoroughly familiar to the student at this level. The self-learning techniques conserve faculty time and maximize the value of the student's time in patient care areas where teaching space may be crowded because of many other health science students receiving clinical instruction in the same setting.

In all clinical teaching, the individual patient is our focus. The medical problems which are diagnosed, the medications prescribed and all other elements of the patient's care are of significance to the instructor and student. For this reason, the patient's chart, which contains all this information, is our principal teaching tool. The problem oriented medical record (POMR) is particularly useful in teaching students the basis for the medications prescribed. The monitoring of any patient's drug therapy should follow a well developed system for student review, utilizing the relevant information recorded in whatever charting system is being used. The pharmacy student's attention should be keyed to the most appropriate use of drugs in individual patients. In the daily monitoring process, the student should develop his or her skills in: (a) problem identification, (b) problem solving, and (c) communications. This presumes that the student has the prerequisite knowledge to develop these skills in clinical pharamcy, i.e. has acquired the necessary "data base."

In developing these analytical, synthesizing and communicating skills, there should be a guidance system developed by the instructor which all students follow in their monitoring of each patient's drug therapy. This should be a process of logical reasoning which results in some form of drug communications presented either verbally or in writing as a consult. Such documentation of patient review also serves well the process of evaluating the progress of each student which is my next and final point.

## 5. Evaluation

The evaluation of student performance in a clinical practice setting is inherently more difficult than one experiences in examining students to determine their acquisition of basic knowledge following lecture presentations. In the clinical setting we are evaluating behaviors which relate more to performance skills in applying knowledge than we are the mere acquisition of knowledge itself. More specifically, we are assessing the student's ability to: (a) identify potential drug related problems; (b) recommend reasonable solutions or alternative approaches to the safe and effective use of drugs, and (c) derive and communicate appropriate drug information when and where it is needed via verbal and written responses.

As mentioned earlier, we should envision the development of these skills in progressive steps throughout the curriculum. For each step or level, we should have clearly defined goals and objectives expressed as expected competencies to be achieved for that level of experience and learning.

A consistent method or methods of evaluation should be applied for all students at each level. Our purpose is to make the evaluation process as uniform and objective as possible. Standard criteria should be developed for measuring performance skills at each particular step or level of learning, again, based upon the expected competencies to be achieved at that level. The uniform use of patient monitoring record forms referred to earlier, provides a good tool for evaluating the progress of each student in a consistent manner. The rotation of students to clinical faculty members in other practice settings provides even greater input to the evaluation process and tends to dilute out any subjective bias that may be present.

Several methods of direct examination are utilized. Some prefer written examinations (objective type) to determine the student's mastery of all the essential facts, skills and concepts necessary to practice at a level of competency expected at that particular level. Others will supplement the written examinations with verbal challenge sessions in which the student is expected to identify a particular drug related problem and provide logical solutions for handling the problem. The latter type of examination is obviously a better measure of rational thinking and self-expression.

Whatever system of evaluation is utilized, it should be sensitive enough to detect learning and behavioral deficiencies as well. This serves a diagnostic purpose and allows the faculty to better tailor the learning experience to each student's particular needs.

In conclusion, I want to emphasize the very complex nature of clinical instruction. The problems we encounter are largely ones of integration: integration with all subject matter of the pharmacy curriculum; integration of clinical instructors as pharmacy faculty members and medicine colleagues; integration of pharmaceutical education within the patient care environment; integration of experiential learning to develop practice skills with previously acquired drug knowledge; and finally, the integration of evaluative methods for student performance with clinical care responsibilities. Despite all of these integrative relationships which have truly challenged us in pharmaceutical education, we have done remarkably well. Most of the role models described today would not have existed 10 or 12 years ago. We have demonstrated a capability for clinical practice and teaching which I'm confident is here to stay. It was, in fact, just ten years ago that I stood before a national audience and predicted that "as the distribution of drugs becomes more highly organized and technical control systems more exacting, the dispensing of drug information may assume the more important role of the professional pharmacist ..." You know, I think we are at least half way there.

# CLINICAL PHARMACY EDUCATION: HOW TO DO IT

Presiding:

William J. Kinnard, Jr.
Dean, School of Pharmacy
University of Maryland
President-elect, AACP

# ADMINISTRATION

William A. Miller, M.Sc., Pharm.D., Associate Professor, College of Pharmacy, University of Tennessee

It is a pleasure for me to be here this afternoon to talk about clinical pharmacy education. As I thought about my presentation I asked myself this question, "What are the essential things that I must do to effectively administer a clinical pharmacy education program?" I concluded that the basic principles of management and administration used in any other multi-faceted program must also be used in order to effectively administer a clinical pharmacy education program. These principles center around five basic management functions; namely: planning, organizing, implementing, directing, and evaluating. I will address myself to these five management functions as applied to clinical pharmacy education programs.

## What must be planned for?

During the 1960's clinical pharmacy programs were begun without a great deal of planning because we were unsure of the objectives, and public need for clinical education. After more than a decade of experience we can now more carefully plan or forecast the types of pharmacists needed by society, and the types of educational programs needed to educate pharmacists. I urge each college of pharmacy to establish some short and long range clinical pharmacy education plans for the future. You should answer some of the following questions as you prepare your plans:

1) What is the definition of pharmacy practice at the national, regional, state, and college level? Now? 1985? 2000?
2) What is the definition of clinical pharmacy practice at the national, regional, state, and college level? Now? 1985? 2000?
3) What specific clinical services do you want your graduates to be able to provide? Now? 1985? 2000?
4) What curricular approaches will you use to educate your graduates to be able to provide these clinical services? (e.g., externships, clerkships, modular education, competency-based education, etc.)
5) What specialities exist in pharmacy practice today? In the future what specialities will emerge?
6) What facilities and equipment will be necessary to provide the desired clinical pharmacy education program?
7) What types and number of faculty will be required to provide the clinical pharmacy program?
8) How will your clinical pharmacy education program be financed?
9) Should your college develop a Doctor of Pharmacy program with a major emphasis on clinical science and practice?
10) What are the characteristics that presently distinquish the Doctor of Pharmacy graduate from the Bachelor of Science graduate?
11) Are there any differences in the pharmacy services provided by Doctor of Pharmacy graduates versus Bachelor of Science graduates?

12) Should your college offer only the Bachelor of Science degree? Only the Doctor of Pharmacy degree? Both the Bachelor of Science and Doctor of Pharmacy degrees?
13) What is a clinical pharmaceutical scientist? How are clinical scientists educated?
14) To have an effective clinical pharmacy education program is it necessary for the college to provide pharmacy services in ambulatory and institutional settings?
15) What types of practitioner-faculty role models will be needed for your clinical education program?
16) Should the college develop post-graduate clinical education and training programs? (residencies, fellowships).

I shall attempt to give you my perspective on some of these important questions that should be answered during the planning of your clinical pharmacy education program.

I believe you will find concensus among pharmacy educators about the following points concerning pharmacy practice and clinical education.

a) Clinical pharmacy education places an emphasis on the patient, the patient's disease condition, and interdisciplinary care as well as being drug product oriented.
b) Clinical pharmacy practice is not limited to a particular environment. It can be practiced in both ambulatory and institutional environments conducive to clinical practice.
c) All aspects of contemporary practice are not clinical, some are technical, some are managerial, some are communicative, etc.
d) Contemporary pharmacy practice currently emphasizes the technical functions involved in stocking, preparing, and dispensing drugs.
e) Future pharmacy practice should emphasize clinical functions. The pharmacist's merchandizing and technical functions should be minimized.
f) All colleges of pharmacy will place a greater emphasis on clinical pharmacy education in the future.

Concensus has not been reached on how much emphasis should be given to clinical pharmacy education! How to go about clinical pharmacy education! And whether all colleges should eliminate their Bachelor of Science program and convert to the more clinical Doctor of Pharmacy degree program.

From a realistic viewpoint, I do not personally feel that it is in the best of interest of society or pharmacy to rapidly eliminate the Bachelor of Science program in favor of the Doctor of Pharmacy program as our sole professional degree. From an idealistic viewpoint, I believe that all pharmacists should ultimately practice as do a few of our current clinical practitioners with the Doctor of Pharmacy background. However, it seems fallacious to assume that we can rapidly convert pharmacy practice to the type of clinical practice exemplified by these few practitioners by simply converting to a highly clinical Doctor of Pharmacy program. I urge each college to address itself to the following questions concerning how much emphasis should be given to clinical pharmacy education, and whether your college should eliminate the Bachelor of Science program in favor of a Doctor of Pharmacy program.

a) Is the primary educational objective of your college to prepare pharmacists for contemporary practice in community and hospital settings? If affirmative, then it would seem inappropriate to offer the clinical Doctor of Pharmacy degree as the sole professional degree of the college.

b) What type of leadership has your college provided to change pharmacy practice at the city, state, and national levels? This leadership will be necessary if pharmacy practice is to change significantly and enable your graduates to utilize their clinical education.

c) Is your college further contributing to pharmacy's manpower problems by producing too many pharmacists who are over-educated and under-utilized as health professionals?

d) Should your college develop a pharmacy technician education program to replace or assist pharmacists involved in drug dispensing?

e) Is your college avoiding the issue of pharmacy technicians and drug dispensers because of adverse political problems that would ensue from community and hospital pharmacists, state boards of pharmacy, and state pharmaceutical organizations?

f) Has your college developed a Doctor of Pharmacy program that emphasizes new clinical roles for Doctor of Pharmacy graduates, but ignores contemporary pharmacy practice?

It is my feeling that within the next ten to fifteen years, all colleges of pharmacy will make the decision to initiate a required Doctor of Pharmacy program. This will lead to highly educated and trained clinical practitioners. It is my feeling, however, that society will not be able to support these doctors to perform merchandizing and drug dispensing activities. As controversial as it may be, a second level of pharmacy manpower must develop before colleges can totally convert to the Pharm.D. as the sole professional degree. This individual, call him an aide, dispenser, or technician will have much less education that the Pharm.D. graduate. Education programs for technicians should be provided by colleges of pharmacy to ensure that pharmacy continues to assume strong leadership for drug use control. Pharmacists should not abdicate their responsibilities for drug dispensing, but should work with pharmacy technicians, just as dentists work with dental assistants, and registered nurses work with licensed practical nurses.

There are numerous obstacles to the development of two levels of pharmacy manpower (i.e., the pharmacy technician and the Pharm.D. pharmacist). However, they are not insurmountable. Colleges of pharmacy must provide the necessary leadership to accomplish the following:

a) Development of educational programs for pharmacy technicians who will assume major responsibility for drug dispensing.

b) Development of reimbursement mechanisms for the provision of clinical pharmacy services that are not directly related to drug dispensing.

c) Development of financial means for costs of clinical pharmacy education and Doctor of Pharmacy degree programs.

d) Improvement of the public, government, institutional, and health professions perception of the value of pharmacy services.

e) Change the standards of pharmacy practice from their current emphasis on technical functions to professional functions.

f) Eventual disaccreditation of those colleges that cannot provide either technician or Doctor of Pharmacy degree programs.

Once these objectives are accomplished we will have paved the way for clinical pharmacy practice by all pharmacists.

If one uses the criteria for pharmacy specialties prepared by the APhA Task Force on Specialties in Pharmacy it is doubtful whether any true pharmacy specialties can at this time be established. However, it is quite apparent that a number of specialties are rapidly emerging, namely:

1) Mental Health Pharmacy Practice
2) Radiopharmacy Practice
3) Primary and Maintenance Care Pharmacy Practice
4) Pediatric Pharmacy Practice
5) General Medicine Pharmacy Practice

Individuals emerging as specialists have acquired their expertise primarily via advanced professional education, post-graduate residency programs, and through extensive experience in a specialized practice area. I urge colleges of pharmacy to assume responsibility for the development of post-graduate residency and fellowship programs for individuals interested in specialization.

How Should the Clinical Pharmacy Education Program be Organized and Directed?

At the University of Tennessee we have recently changed the organizational structure of our college to more appropriately recognize pharmacy practitioner faculty members from a teaching, service, and research viewpoint. Formerly most practioner faculty appointments were in the Division of Clinical Pharmacy a part of the Department of Pharmaceutics. Under our new organizational structure the Division of Clinical Pharmacy has been elevated to departmental status, and is now called the Department of Pharmacy Practice. We decided not to call the new department the Department of Clinical Pharmacy because this implied that clinical pharmacy was different than community or hospital pharmacy. We also recognized that in the future clinical services should be provided by all pharmacists in all professional settings. This is the primary reason that we have a required clinical component in both our Bachelor of Science and Pharm.D. curriculums.

I urge each college to develop an organizational structure that will allow you to coordinate all aspects of "practice" from a teaching, service, and research viewpoint. This will allow your college to change their short and long term "practice" objectives as pharmacy standards of practice change and as society perceives the need and reimburses pharmacists for new types of pharmacy services. For example, let me use the case of drug interactions to illustrate my point. In the 1960's practitioner and educator leaders began to emphasize the importance of the pharmacist's role in detecting drug interactions. Yet in a study by Knapp few pharmacists were found to actually detect well known drug interactions when presented prescriptions in community pharmacies. In the 1960's some pharmacists even questioned if it was their responsibility to know whether there was a potentially clinically significant drug-drug or drug-disease interaction. Some of the earlier "clinical pharmacists" in hospitals were preoccupied with drug-interactions and adverse drug reactions. By the early 1970's it became apparent that all pharmacists should be educated about drug interactions, and colleges of pharmacy developed didactic and practical experience courses dealing with drug interactions. Today, few pharmacists would disagree with the statement that all pharmacists should be able to detect drug interactions as a part of the standards of practice for pharmacy. The point I wish to make is that in the college where clinical, hospital, and community aspects of the curriculum are segmented and uncorrdinated it is difficult for the college to incorporate new concepts such as drug interactions, that are initially applied in more advanced practice settings, but which eventually become a standard of practice for all settings.

The college should name one individual faculty member with overall responsibility for coordination of pharmacy practitioner teaching, service, and research programs. This individual should be designated as Coordinator, Division Chairman, Departmental Chairman, or Assistant Dean depending upon the organizational structure of the college. Clinical faculty should not be placed in a department or division originally designated for a particular basic science group (e.g., pharmaceutics, pharmacology, etc.). A new department or division should be created for practitioner faculty members. This will enable clinical faculty to more effectively develop teaching, service, and research programs. This will allow them more direct input into the organizational and decision making activities of the college.

It is essential that students become interdisciplinary and team oriented during their clinical pharmacy education. Your clinical program must be understood, supported, and coordinated with other health professionals practicing and/or teaching in the same ambulatory or institutional settings. Clinical practitioner educator role models must be integrated as team members in these practice settings. Faculty role models must have defined team responsibilities. They should be held accountable to the physician team leader for patient services rendered.

It is obviously easier to develop a clinical pharmacy education program in a health sciences center committed to interdisciplinary health education and team care. Some colleges have successfully developed clinical education programs through affiliations with other health science colleges, institutional, and ambulatory facilities. I urge these colleges to consider more than an affiliation agreement for teaching purposes. Too often clinical faculty in affiliated hospitals or ambulatory settings are not active practitioners and as such are not effective role models due to the lack of well defined service responsibilities. Affiliation agreements should state the specific services that will be provided by the faculty role model in addition to teaching responsibilities. The college may even develop a service contract with the affiliated hospital for services provided by the faculty role models. One measure of the value of the clinical services provided by clinical faculty is whether hospital or ambulatory care administrators are willing to pay for these services using patient revenues. Service contracts or agreements will enable the college to increase the number of role models available for clinical teaching. Excluding administrative faculty, individual clinical faculty members should not be paid completely from service or teaching funds. A balance should be achieved between the faculty members's responsibilities as a teacher, practitioner, and researcher.

### What Steps Should be Followed to Develop and Implement a Clinical Pharmacy Education Program?

I recommend that you consider some of the following steps in developing your clinical pharmacy education programs:

1) Read and study the literature on clinical pharmacy practice and education.
2) Visit and observe established clinical pharmacy practice and education programs.
3) Review your current clinical pharmacy education program.
4) Identify the clinical pharmacy practice and education programs that will be provided by the college.
5) Establish the relationship between clinical pharmacy education and other curricular areas of the college.
6) Establish the relationship between clinical pharmacy education and other health science education programs (i.e., nursing, medical, and dental) on your campus or affiliated with your college.
7) Set some short and long term goals and objectives for your clinical pharmacy education program. Determine which aspects have the highest priority.
8) Determine which approach is most feasible for the development of your program.
9) Determine what resources will be required to implement your program.
10) Determine how the proposed program will effect other disciplines.
11) Prepare a proposal and obtain approval for the program via established channels.
12) Implement the program in one or more areas (e.g., general medicine, pediatrics, psychiatry).

13) Expand the program into other areas.

14) Evaluate the outcome of the program.

From the Institute of Medicine Studies on the cost of health education we can conclude that clinical education in medicine is expensive due to the small student-faculty ratio required in the clerkship settings. The same is true for clinical pharmacy clerkships.

Colleges of medicine use a pyramid system to provide patient care and medical education (See Figure 1).

This same type of pyramid system is being used by a number of colleges of pharmacy (See Figure 2). Teaching and service is provided at all levels of the pyramid. In process review and quality, control is coordinated from the top to the bottom of the pyramid.

At the University of Tennessee we have developed the following faculty-student clerkship teaching guidelines. Each full-time faculty practitioner role model is responsible for a minimum of two Doctor of Pharmacy and two Bachelor of Science clerkship students each time the clerkship is offered. Residents are now being added into our pyramid system. With the addition of residents we expect that each faculty role model will be able to take responsibility for one resident, three Doctor of Pharmacy, and four Bachelor of Science clerkship students. These guidelines are maximum student quotas. Often faculty role models have less student teaching commitments. In some instances we can not follow these guidelines because a clinical facility can not accommodate this number of pharmacy students in addition to other health practitioners and students.

Using these guidelines we are currently able to provide our Bachelor of Science students with six-hundred hours of required clerkship experience in ambulatory and institutional settings. In addition, we are able to accommodate 15-20 Doctor of Pharmacy students on clerkships at any one time. Each Pharm.D. graduates with a minimum of 2500 hours of clerkship experience.

I urge each college to consider using the pyramid system for clerkship teaching and service. This system will help you optimally utilize your faculty resources while minimizing the costs of clinical education.

Clinical pharmacy education is not solely provided by the clinical faculty. If we agree that clinical education emphasizes the patient, the patient's disease and interdisciplinary team care as well as drugs, then a multidisciplinary faculty must be assembled to achieve our educational goals and objectives. Pathology, behavioral science, clinical pharmacology, pharmacokinetics, toxicology, biostatistics, information science, therapeutics, and clinical clerkships are examples of multidisciplinary curricular areas that have been added to achieve our clinical educational goals. Colleges of pharmacy can not develop a successful clinical program without the expertise provided by individuals with backgrounds in these disciplines. Clinical faculty should primarily contribute to college educational programs by teaching didactic therapeutics

Figure 1

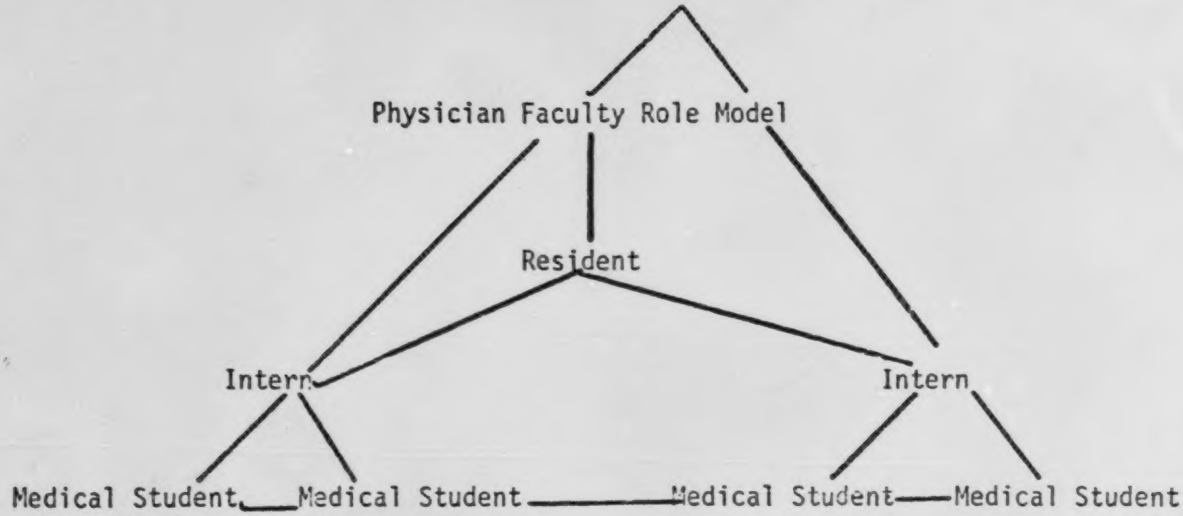
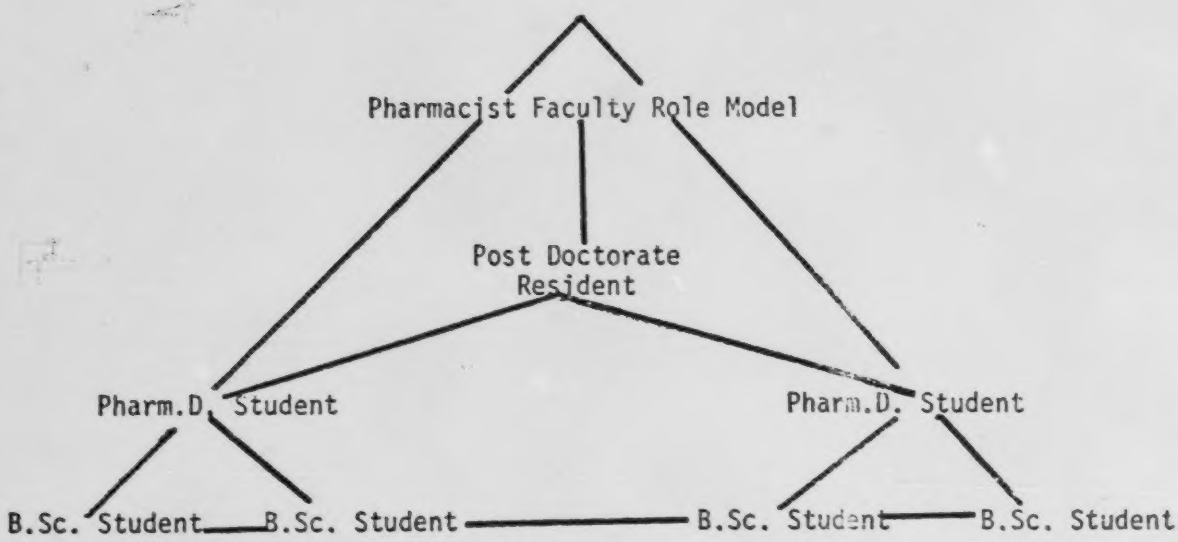

Physician Faculty Role Model
Resident
Intern
Intern
Medical Student
Medical Student
Medical Student
Medical Student

Figure 2


Pharmacist Faculty Role Model
Post Doctorate Resident
Pharm.D. Student
Pharm.D. Student
B.Sc. Student
B.Sc. Student
B.Sc. Student
B.Sc. Student

and by serving as clerkship role models. Clerkships should be used as capstones to both the Bachelor of Science and Pharm.D. program. Didactic course work should be avoided during clerkships to allow students to become full-time members of the team in the respective clerkship setting.

Clinical pharmacy faculty will ultimately have to develop their own body of knowledge in order to qualify as a distinct discipline, comparable to pharmacology, pharmaceutics, pathology, etc. Currently, clinical faculty borrow most of their expertise from clinical pharmacology, clinical medicine, toxicology, and pharmacokinetics. I urge each college to provide the time and resources for clinical faculty to conduct drug therapeutics research. This research will lead to recognition of clinical pharmacy as a distinct clinical science discipline.

How Should Clinical Education Programs be Evaluated?

Colleges of pharmacy are currently using or developing competency-based curriculums. Clinical pharmacy education emphasizes the ability of the pharmacy student to apply his drug knowledge in actual patient situations. Thus the effectiveness of a clinical education program is best judged by determining whether graduates can perform as defined by specific behaviorial objectives. I urge each college to develop a competency-based clinical pharmacy curriculum.

Well, I have enjoyed this opportunity to express some of my views on how to develop a clinical education program. I hope you will find my comments constructive, rather than critical, cynical, or unrealistic. I believe the immediate future of pharmacy practice centers around our ability to effectively define, plan, organize, implement, and evaluate clinical pharmacy education programs. The future of pharmacy education will in-part be shaped by the values of the present and past. However, the way we imagine the future has a powerful impact on the decision and plans we make today. To quote, Alvin Toffler, "All education springs from some image of the future. If the image of the future held by a society is grossly inaccurate, its education system will betray its youth."

# CRITICAL ELEMENTS: BASIC AND CLINICAL SCIENCES

Ewart A. Swinyard*, Ph.D., Professor, College of Pharmacy, University of Utah.

> "What is new and significant
> must always be connected with
> old roots; the truly vital roots
> are chosen with great care from
> the ones that merely survive."

This principle, professed by the composer Bela Bartok, is just as applicable to pharmaceutical education as it is to music. Indeed, it highlights the two most difficult tasks encountered in discussing the subject "Critical Elements: Basic and Clinical Sciences". The first is identifying the "truly vital roots" or critical elements upon which to build a professional program. The second is describing how these critical elements interrelate to form a significant patient-oriented pharmacy program.

It is now abundantly clear that patient-orientation in the pharmacist, the product of our curriculum, is essential to the survival of pharmacy as a profession. It does not follow, however, that the entire curriculum, within the College, must be so oriented. In doing so, one runs the risk of neglecting the one area of expertise that differentiates the pharmacist from the physician; namely, his knowledge of drugs. If the pharmacist knows no more about drugs and therapeutics than the well-trained physician, he can and probably will be replaced by such a person. This thought, however, should not lend solace to those educators who because of personal bias favor the retention of courses which are steeped in tradition, but whose roots will, at best, "merely survive" in the practice environment which lies ahead.

Probably the most difficult problem is to design a curriculum which flows as a continuum from the pre-professional (basic) courses through the professional required (core) courses and into the applied (clinical) courses. This requires careful integration and correlation of a faculty with varied backgrounds and expertise: social and behavioral, biological, and physical scientists at the "pre-professional level"; a blend of biomedical, physical, pharmaceutical, and medical scientists at the "professional core level"; and role models, both pharmacy and medicine, at the applied (clinical) level. It should be noted that the term "basic" has been avoided, except to describe courses in the pre-professional area. This term is divisive for both curriculum and faculty and should not be used to describe an arbitrary division within the professional program.

The critical elements of a 5-year program of study in pharmacy are shown in Table 1. For purposes of this discussion the sequence has been divided as follows: pre-professional (basic) courses, professional core courses, and applied professional (clinical) courses.

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*The author acknowledges with sincere gratitude the many suggestions and contributions of his colleagues in the preparation of this paper.

Table 1.

Critical Elements: Basic and Clinical Sciences

| Pre-professional (Basic) Courses | Professional Core Courses | Applied Professional Courses |
|---|---|---|
| | Biomedical Sciences | |
| General Biology | ← Anatomy | |
| Microbiology Electives | ← Physiology | |
| General Chemistry | | |
| Organic Chemistry | ← Physiological Chemistry | Clinical Pharmacy (clerkships) |
| | Pathophysiology → | |
| | Pharmacology & Therapeutics → | |
| | Pharmaceutical Sciences | |
| Physics | ← Physical Pharmacy | |
| Calculus | ← Pharmacognosy | |
| | ← Medicinal Chemistry | |
| | ← Biopharmaceutics → | |
| | | Community Pharmacy (externships) |
| | Pharmacy Administration & Practice and/or Community Medicine | |
| Communicative Courses | ← Pharmacy Practice → | |
| Electives | Jurisprudence → | |
| | Utilization of Health Resources → | |

The professional core courses have been further divided into biomedical sciences, pharmaceutical sciences, and pharmacy administration and practice and/or community medicine. The direction of the arrow(s) indicate whether the particular course forms a "bridge" or "transition" with either a pre-professional course, an applied professional (clinical) course, or both. The vertical relations among the several disciplines are discussed below.

Although this discussion is concerned largely with the critical elements of the professional core courses and how they relate to the pre-professional and applied professional (clinical) courses, there are deficiencies in the biological and communicative areas in the pre-professional offerings of most colleges that are worthy of comment.

Biological Area. In view of the recognized need to improve the patient-oriented training of the pharmacist, it is a pity that the level and kind of biological training considered acceptable for admission to the professional core courses (3rd year) are generally markedly inferior to those required in the physical science area; the level of expertise required in chemistry provides an excellent example of this disparity.

The level and kind of biology accepted by many admission committees can usually be satisfied by the pre-admission advanced placement tests. Unfortunately, the same general criticisms also apply to many microbiology, anatomy and physiology courses offered at the pre-professional level. This problem can be significantly improved if colleges of pharmacy would indicate in their catalogs the level of expertise and the orientation expected when these courses are accepted as prerequisites to admission to the first professional year of pharmacy study, and in addition, offer a preadmission test, not only in chemistry, but also in general biology, and, if appropriate, anatomy and physiology in order to evaluate the student's pre-professional preparation.

Communicative Courses. Effective communicative skills are essential to clinical practice in either an institutional setting or community pharmacy. Without effective communication the entire concept of clinical training becomes worthless. Although most educators agree that the ability to communicate effectively is a necessary competency for the pharmacist, few use teaching technics which develop these skills.

The pre-professional courses are not specifically directed toward improving communication among professionals or between professionals and patients. Furthermore, the kind of instructional methods and examinations usually employed by instructors in the professional core courses provide little opportunity for the student to gain experience in this area. This deficiency can be improved by more small group discussions and role playing in professional core courses and experience in a drug information and/or poison control center prior to externship and clerkship training. Mention will be made of how additional experience in this area can be incorporated into programs with even limited resources.

Let us now return to the critical elements in the professional core sequence.

## Professional Core Courses

This title is used to indicate the courses all students should be required to take irrespective of their ultimate practice areas. This term refers to the same group of courses which Dr. Millis likens to the "trunk of the tree". Specialization can be accomplished by a series of elective courses which provide the level of expertise required in the applied professional (clinical) areas, such as clinical pharmacy, community pharmacy, etc. Ideally, all professional core courses should be "patient oriented". This is sometimes difficult to accomplish in those courses which provide a "bridge", or "transition" from the pre-professional (basic) courses to the professional core area.

Consideration will now be given to how these courses should be interdigitated and to a brief review of the material that should be covered in each course.

Biomedical Sciences. A strong background in the biomedical sciences (anatomy, physiology, physiological chemistry, pathophysiology, pharmacology and therapeutics) is essential to the pharmacist's role in the appropriate use of drugs in disease-induced abnormalities in individual patients. Anatomy and physiology are usually problem courses.

These subjects can best be taught in a combined course by a pharmacy-physiology trained person with a patient-oriented approach as part of the professional core curriculum. Enough anatomy should be included so that the student will understand functional anatomy and basic terminology. The behavioral objectives of the physiology portion of the course should include a knowledge of function and regulation in the basic organ systmes (cardiovascular, respiratory, central nervous system, renal, endocrine, gastrointestinal, and musculoskeletal). When taught as a combined course, with the objective of teaching the kind of physiology which enables a student not only to understand normal functional physiology, but also those mechanisms important for understanding drug action and the disease process, considerable time can be saved and a much more effective, high-level course presented. However, few colleges of pharmacy can afford this luxury. A reasonable alternative is to work closely with the instructor and encourage this person to teach it from a functional organismal approach, rather than from a philosophical, cellular or molecular point of view. Otherwise, the patient-orientation ordinarily expected in this course must be taught by the instructor in pathophysiology or pharmacology.

Microbiology represents another course which can be taught either in the pre-professional curriculum or the professional core curriculum. All too often this course is taught as an applied science, concerned largely with environmental control of those microbes that affect man's health or his economic welfare, rather than providing an insight into infectious disease, including the action of chemotherapeutic drugs. Once again the level of biological training that a pre-pharmacy student receives is quite dependent upon the level of training offered in this course.

Physiological chemistry (biochemistry) should provide a smooth transition between organic chemistry and human health problems by means of an in-depth discussion of the biochemical processes characteristic of the normal individual. This course should, therefore, interface with organic chemistry, physiology, pathophysiology, and pharmacology. Behavioral objectives include an understanding of the structure of a cell at the molecular level and the role of carbohydrates, proteins and lipids in its structure and function; an understanding of the cell as a functional unit, subcellular organelles, and enzyme pathways and their regulation (including enzyme kinetics, hormonal control, co-factor involvement, etc.); an understanding of maintenance of cell structure and function, including cell division; an understanding of deviations from normal cell function (including disease, genetics, biochemical tests, etc.).

This subject can be made to live if the instructor will relate as many topics as possible to a disease state. For example, during the discussion of metabolic pathways, one can very easily bring in the symptoms of diabetes mellitus after explaining the normal effect insulin imposes on carbohydrates, fats and amino acid metabolism. If the student understands the causes of glycosuria, ketoacidosis, obesity, and cataract formation in the diabetic patient, he or she will also know a great deal about the usual role of insulin.

Pathophysiology provides a smooth transition between the biomedical sciences and the applied professional (clinical) courses. (This cannot be accomplished by the classical course in pathology.) The pathophysiology of disease and the fundamentals of pharmacology must be interdigitated in order to understand drug selection and how to establish therapeutic objectives. This requires close cooperation between pharmacology and pathophysiology. In order to accomplish this, the general pharmacologic principles, including autonomic pharmacology and immunology, should precede pathophysiology. Thereafter, the background material about a disease state should be covered first in pathophysiology before discussing in pharmacology the drugs used in that pathologic condition, the therapeutics, and drug interactions. The behavioral objectives of pathophysiology include the following: the student will be able to describe the epidemiology of a given disease; the student will be able to describe the signs and symptoms of the disease; the student will be able to describe the clinical course of the disease; and the student will be able to describe the pathophysiology of the disease.

Despite the tendency among a large segment of clinical pharmacy faculty to teach all segments of the clinical area, instruction in this course can be markedly enhanced by the use of physicians experienced in teaching various portions of this course. The role of the clinical pharmacy instructor is largely one of correlation and working in the small group sessions described below. It is important in pathophysiology to supplement the usual didactic instructional work with a one or two hour recitation period a week during which time students and faculty (pathophysiology, pharmacology, and clinician) can interact on a more personal basis. This kind of interaction has been found to be extremely beneficial and permits a more in-depth understanding of various aspects of pathophysiology, pharmacology, therapeutics, and drug interactions than can otherwise be accomplished.

Pharmacology must be carefully correlated, not only with pathophysiology, but also with physiology, biopharmaceutics, and medicinal chemistry. Because of this, it should provide a smooth transition and one of the "broadest bridges" which connects the professional core courses with the applied professional (clinical) courses.

This was described most beautifully in 1940 by Drs. Louis S. Goodman and Alfred Gilman in the preface to the first edition of The Pharmacological Basis of Therapeutics. (This writer has taken some editorial license which is indicated by the bracketed words.)

"Although pharmacology is a basic (pharmacuetical) science in its own right, it borrows freely from and contributes generously to the subject matter and techniques of many (pharmaceutical) disciplines, clinical as well as pre-clinical. Therefore, the correlation of strictly pharmacological information with (pharmacy) as a whole is essential for proper presentation of pharmacology to (pharmacy) students and (pharmacists). Furthermore, the reinterpretation of the actions and uses of well-established therapeutic agents in the light of recent advances in the medical (and pharmaceutical) sciences, is as important a function of pharmacology as is the description of new drugs. In many instances, these new interpretations necessitate radical departures from accepted but outworn concepts of the actions of drugs. Lastly, the emphasis throughout the book, as indicated in its title, has been clinical. This is mandatory because (pharmacy) students must be taught pharmacology from the standpoint of the actions and uses of drugs in the prevention and treatment of disease. To the (pharmacy) student, pharmacological data *per se* are valueless, unless he is able to apply his information in the practice of (pharmacy). This book has also been written for the practicing (pharmacist), to whom it offers an opportunity to keep abreast of recent advances in therapeutics and to acquire the basic principles necessary for the rational use of drugs in his daily (clinical) practice."

The abcve objectives, recorded over a third of a century ago, clearly describe how this course should function in the training of the pharmacist of today.

In its function as a "broad bridge" between the professional core courses and the applied professional (clinical) courses, pharmacology and therapeutics interface with numerous biomedical disciplines. How this can be done is best shown by listing topics that should be covered under diseases of the cardiovascular system. The suggested hours to be devoted to each topic and the instructor (s) involved are shown in parentheses.

Antihypertensives (2; pharmacologist)
Therapeutic Conference: Therapy of Hypertension (2; clinician*)
Pharmacotherapeutics--drug interactions (1; pharmacologist and/or clinician*)
Anticoagulants and Vitamin K (2; pharmacologist)
Drugs and Lipid Metabolism (2; pharmacologist)
Therapeutic Conference: Coronary Artery Disease (2; clinician*)
Cardiac Glycosides (2; pharmacologist)
SAR of Cardiac Glycosides (1; medicinal chemist)
Diuretics (2; pharmacologist)
SAR of Diuretics (1; medicinal chemist)
Therapeutic Conference on Congestive Heart Failure (2; clinician*)
Cardiac Glycosides: Pharmacokinetics and dosage pharmacotherapeutics (2; pharmacologist and/or clinician*)
Antiarrhythmics (2; pharmacologist)
Therapeutic Conference: Therapy of Cardiac Arrhythmias(1; clinician*)

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*M.D. or Pharm.D.

With this kind of integrated approach, the student not only benefits from the personal experience of the various instructors, but also benefits from the more practical approach to pharmacology and therapeutics. Moreover, it serves to enlarge the student's view of the kinds of drug and therapeutic problems likely to be encountered in his or her clinical training.

Upon completion of the biomedical science sequence described above, the student should be able to: understand the structure of the body at both the gross and molecular level; understand the body as a complete and regulated functional unit; understand the changes that occur in the body as a result of disease, drugs, or other foreign compounds; and understand the effects of pharmacological intervention in the disease state and be able to anticipate and prevent the untoward consequences of such intervention.

## Pharmaceutical Sciences

*Physical Pharmacy* is an excellent example of a course in problem solving. This discipline deals with the physical chemical properties of drugs and related compounds. It serves as a "bridge" between the pre-professional courses in mathematics, chemistry and physics and the professional core courses, especially biopharmaceutics, medicinal chemistry, and pharmacology. It is the objective of this course to relate such concepts as intermolecular forces, solubility, equilibria, partitioning, diffusion, protein binding, chemical kinetics, etc. to the bioavailability of the drug entity used in the treatment of disease and to factors which determine whether the dosage form selected will be optimally utilized.

A frequently overlooked benefit derived from this course resides in the learning process essential to the mastery of the subject; the envisionment of relatively complex phenomena, to the ability to extrapolate and apply previously learned ideas, and the formulation of appropriate conclusions. Thus, the instructor in this course has an unusual opportunity to enhance the student's analytical and communicative skills. Because of its emphasis on drug delivery, it provides a useful background for clinical practice.

*Pharmacognosy*, a discipline steeped in the history of pharmacy, means many things to many people. To some it refers to the "classical pharmaceutical botany", to others it is "natural products chemistry", and to others it may mean something else. In this presentation it will be considered "natural products chemistry". When viewed from this perspective, it is related to medicinal chemistry and interfaces in a very important way with a number of other disciplines.

How important are natural products in the training of the pharmacist. All immunizing biological products and many other drugs are obtained from natural products. *All* infections, *most* allergies, and *many* toxic diseases are caused by natural products. Moreover, food drug interactions, drug abuse and social customs (alcoholic beverages, coffee, tobacco, etc.) involve substances derived from natural sources.

These observations not only justify including natural products chemistry as a professional core course, but also suggest the way it should be presented. The modern approach deals not only with the chemistry of natural products, but just as importantly with the biochemical, biological, and economic aspects of the subject. When approached from this point of view, it provides a "bridge" between the pre-professional courses in biology and chemistry and several of the professional core courses, such as medicinal chemistry, biochemistry, immunology, pathophysiology, and pharmacology.

Medicinal Chemistry is another "bridge" course that is most frequently concerned with the which, where, and how the principles of organic chemistry relate to the patient-oriented training of the pharmacist. The which principles include nomenclature, stereochemistry, acid-base theory, salt formation, solubility, and functional group chemistry. The where principles include drug nomenclature, drug design and development, drug formulation and production, drug control and administration, and structure-activity relations. The how principles are applicable in various areas of pharmacy (community, institutional, and clinical) both for the provision of technical pharmacy services and for the retrieval, assessment and dissemination of drug information.

There is a hazard in the above approach. This resides in the tendency to teach medicinal chemistry as merely an extension of organic chemistry, rather than from the more relevant and exciting biological point of view. Two or three examples will illustrate this point. In drug-receptor interactions, the receptor is all important. The challenge to medicinal chemistry is to explain why certain isomers, various substitutions, etc. prevent, decrease, or increase the reaction. Another example relates to the pharmacokinetics of absorption, distribution and excretion of drugs and how medicinal chemistry relates to these phenomena. The medicinal chemistry instructor can make a significant contribution by emphasizing how chemical modifications of the drug molecule can alter these phenomena. A logical extension, based on the principle that a well-absorbed compound is well-reabsorbed, and difficult to excrete by the kidney, leads to a discussion of the need for and the chemistry of metabolism. The medicinal chemist should point out that metabolism is not merely oxidation, reduction, or hydrolysis reactions, but that these chemical reactions are important because they create more polar compounds and enhance excretion. Finally, medicinal chemistry of extreme relevancy to the clinically-oriented student can be achieved by providing a means of predicting drug effects, both therapeutic and toxic, i.e., encouraging the student to remember prototype structures and seeing other drugs as modifications of these prototypes, rather than viewing each new drug as representing entirely new chemistry and pharmacology. Such an approach should be most exciting to both the instructor and the student.

Biopharmaceutics (Pharmacokinetics) is a pharmaceutical science which borrows freely from and contributes generously to other professional core courses as well as to the applied professional (clinical) courses. It borrows from physical pharmacy, medicinal chemistry, physiology, pathophysiology and pharmacology; it contributes to clinical pharmacokinetics and to improving the drug dosage forms and to obtaining optimal therapeutic drug effects. In order to accomplish this, emphasis is placed on the pharmacokinetic information necessary to compute the correct dosage regimen for individualized drug therapy. For this, consideration must be given to many physiological factors such as body weight, age, sex, kidney, liver, and cardiac functions as well as the pathological state of the patient in order to derive an individualized treatment regimen. Moreover, students must be taught the importance of monitoring plasma blood levels in order to make appropriate adjustments in drug dosage and to achieve the best possible drug therapy.

This science is also an invaluable tool for monitoring the relation between the nature and intensity of drug effects induced by manipulations in the form of the drug (ester, salt, complex, etc.,), physical state (particle size and surface area), drug delivery system and any adjuvants, and the pharmaceutical process used to make the dosage form. Thus, biopharmaceutics is not only an important professional core course, but also serves as a "bridge" with pre-professional as well as applied professional (clinical) courses.

### Pharmacy Administration and Practice and Community Medicine

Despite the possibility that this topic might infringe upon the subject matter assigned to another member of the panel, the critical elements of the professional core courses would not be complete without some mention of pharmacy practice, pharmacy jurisprudence, and utilization of health resources.

Pharmacy Practice occupies a unique position among the professional core courses. As a professional core course it provides a firm "bridge" or orientation between both pre-professional courses and applied professional (clinical) courses. The first course in pharmacy practice should be offered the first quarter (or semester) of the first professional (third) year. This position is mandatory for two reasons: (1) Many states permit registration as an intern pharmacist during the first professional year of study. (2) This course introduces students to dosage forms and provides the basic information required for them to interact ethically, effectively, and legally with preceptors, other health professionals, patients, colleagues, and faculty members. Moreover, the laboratory portion of this course should not only cover the basic technics and manipulations involved in dispensing a prescription, but should also provide at least some exposure to community pharmacy, hospital pharmacy, and clinical practice. This kind of orientation is invaluable since it provides some understanding of what is expected of him or her as an intern and student, and it also assists the student in selecting the area of pharmacy in which to specialize.

The second course in pharmacy practice should be offered in the third quarter or second semester of the second professional (fourth) year of study. This position in the curriculum is important since the principal objective of this course is to synthesize all previous information essential to pharmacy practice and prepare the student for the more structured training in clinical or comunity pharmacy presented in the final year of a five-year program. Accordingly, major emphasis is placed on developing manipulative skills, preparation of more sophisticated dosage forms, and a thorough understanding of the advantages and limitations of each.

The laboratory material is of such a nature that the instructor can introduce patient profile records and have the student maintain them according to the prescriptions handled during the course. It also provides an unusual opportunity to increase the communicative skills of the student by a professional-patient role playing technique. By means of this teaching approach, the student can gain experience in taking patient drug histories, conducting patient interviews, explaining the need for strict patient compliance in order to achieve optimal results of the medication in question, and offering other advice and counsel relative to how, when and with what to take the medication and, for example, in the case of depressant-type drugs, caution the patient with regard to driving an automobile or operating complex machinery while on such medication. Other important pharmacist-patient types of information, including the practical aspects of drug interactions and how to relate to both the physician and the patient in these matters, lend themselves to this type of instruction.

When pharmacy practice is approached in this manner, it serves as a real "bridge" course preparing the student for work in the applied professional (clinical) area, such as the clinical pharmacy (clerkship) program or community pharmacy (externship) program; the latter should involve an in-depth, one-to-one training by a preceptor for 40 hours a week for four weeks in three different practice settings (community, hospital, and clinical pharmacy).

Pharmacy Jurisprudence should provide not only the necessary details concerning licensure procedures, handling and dispensing of drugs and related items, and other housekeeping matters, but also an understanding of the total legislative and judicial process. This is particularly important as pharmacy education and practice evolves into more direct patient involvement.

It is important for the pharmacist to understand fully his functional role in total patient care and how he interfaces with other health professionals within a legal and ethical framework. Ideally, it would be appropriate to have a separate course in "Ethics". Since few colleges can afford such a luxury, the essential information in this important course can be included in the first course in pharmacy practice as well as in more depth in pharmacy jurisprudence. It is also important that the student have sufficient understanding of the legislative process and the philosophy of laws to be able to influence changes.

From the point of view of the patient, the pharmacist must perform in a professional manner. Whether this relates to the mechanics of drug distribution or to the more sophisticated forms of practice such as monitoring of drug therapy it must be performed within legal guidelines. As the level of patient involvement increases it will become increasingly important for the pharmacist to influence appropriate authorizing legislation.

Utilization of Health Resources is a vital "new root" in the pharmacy curriculum. The pharmacist is the health professional who has the most direct contact with a large segment of the population and, therefore, may provide a necessary and important service to the community. This service is contingent upon understanding the available health resources and how they can be utilized. The objectives of this course include: How to determine from a client the nature of the health services needed; how to describe the services of the appropriate agency (ies) to the client; and how to inform the client of the procedures for obtaining the agency(ies) services. In addition, the student learns the processes of exploratory inquiry. The latter is accomplished by obtaining a first level of personal familiarity with selected health agencies within the area. In general, these can be divided into four groups: (1) service institutions (mental health, medical care, drug abuse care, and ambulatory medical care), (2) educational institutions (federal, state, local, and private), (3) economic institutions (commercial), (4) social groups (American Cancer Society, Heart Associations, Arthritis Foundation, etc.).

Each student is assigned several health agencies to study and is required to study one in depth. The initial approach involves library research to become acquainted with the reported functions of the agency(ies) under study. The student then formulates open inquiry questions relative to types of service, persons eligible for such service, cost of services, and mechanism of entry. This pre-study is then followed by a personal visitation of the several agencies and ten hours of volunteer service in the agency of the student's choice. This experience is followed by post-study during which the student organizes his experience with the agency. The observations and findings are then shared with other members of the class by means of a simulated pharmacist-client interaction.

The success of this type of instruction depends upon the instructor having an in-depth knowledge of all agencies assigned in order to assure the dissemination of accurate information. Student benefits derived from this approach include not only achieving the benefits described above, but also a more professional approach to active inquiry, as well as improved communicative skills. Moreover, the student learns how to evaluate an issue, determine alternative ways of resolving the issue, and make a choice after taking into consideration his own values as well as those of society. The last two periods are devoted to an in-depth class discussion on "how the pharmacist can implement this service in the community" in which he/she elects to practice and a summary of the course.

In conclusion, it should be remembered that this presentation has been limited to the critical elements of the pre-professional (basic) courses and the professional core courses. "The truly vital roots(courses) have been chosen with great care from the ones that merely survive." Emphasis has been placed on how the pre-professional or basic courses relate to the professional core courses and how the latter relate to the applied professional courses (clinical pharmacy and community pharmacy). In the discussion of each course, primary attention has been devoted to how they relate to each other and to the total program and how they should be presented, even with limited resources. Where more than one resource may be available, the advantages and disadvantages of each have been discussed. The optimal approach based on the experience and personal bias of the author has also been presented.

# SUPPORTING SERVICES

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Our most difficult task in writing this paper was defining a "supporting service." We have decided a "service" shall be defined as a function which is performed by a professional for a patient in order to treat or prevent disease. A "supporting service" is rendered for a health professional, and not directly for a patient. It allows the professional to perform more efficiently or more effectively.

According to our definition, then, we will not consider an IV admixture service a supporting service because the patient is the ultimate consumer of the service. On the other hand, a drug information center will be considered a supporting service becuase the users of this service are most often professionals (rather than patients) whose performance is made more efficient and more effective because they receive this assistance. We admit that this distinction is somewhat arbitrary, but it helps us to narrow the scope of our discussion. Many of our remarks will apply to both clinical and supporting services.

Implicit in our definition is the fact that a supporting service satisfies a need. A clinical pharmacokinetics laboratory, for example, is not a supporting service if it is instituted only because other colleges have one. There are legitimate reasons for establishing an innovative and experimental service, but we deceive ourselves if we claim we are supporting the clinical pharmacist if we give him a service he has not requested and does not use. Too many "supporting services" must work hard to generate a demand for their services!

The value of some supporting services may be most significant at the beginning of the program, when clinically trained personnel are still in short supply at the institution. The clinical personnel should not be encumbered with duties that could be performed by others if they could use this same time for patient care and educational responsibilities. It is ridiculous for the clinical pharmacist to fill patient medication cabinets or prepare drugs in unit dose packages, for example, if the time he spends doing secretarial work could be used elsewhere. Administration may be able to purchase more clinical service for less money by adding supportive personnel than by adding clinical staff.

Other so-called supporting services actually require clinically trained pharmacists in order to operate. Perhaps initiation of specialized services, that require individuals with education and experience equilvalent to those who provide more basic clinical services, should be delayed until that more basic service is provided throughout the institution. It may not be wise to start a pharmacokinetics laboratory in a hospital that has a clinical pharmacist on some untis, but not on others. Likewise, from the viewpoint of the educator, it may not make a great deal of sense to institute a sophisticated and specialized clinical experience for a part of a pharmacy class, when more basic clinical experiences are still elective, rather than required, for every student of the college.

We are concerned about the loss of credibility we suffer when we have a double standard, giving clinical services to some patients, but not others, and providing clinical experiences for some students, but not others. Too often, in our rush to provide the latest and the best, we make great strides forward in a single given area, rather than improve that minimum level that is available to all.

Since we have mentioned specialization, let us expand on this for a moment. American pharmacy is currently examining the roles that pharmacists assume and can be expected to assume in the foreseeable future. Of course, this is tied together with the educational processess that equip individuals to carry out one of these roles. Although studies are being conducted and opinions are being voiced, I think it is safe to say that we have not reached a consensus on the role of the pharmacy specialist, the training he should have, and the certification process that would assure a uniform level of competence. In fact, we are still struggling with these issues at the general practitioner level.

Henry Ford developed a better way of building automobiles. Instead of having a group of men work on his car until it was finished, a man was given a job to do on each car as it rolled past him on the assembly line. A man who used to put the entire automobile together now did nothing but tighten the bolts that held on the wheels. This man, whose job is but a fraction of the whole task of putting an automobile together, might be providing a "supporting service." I don't think he would have the audacity to call himself a "specialist!"

So it is with pharmacy. Technical and clerical personnel can take time-consuming tasks from us and improve our efficiency. We no longer type labels or fill the unit dose cart. We have more time to spend in areas which require professional judgement. We are freed by a supporting service. We have not created a specialist.

However, there is a point where those tasks that can only be done by a pharmacist are consolidated, and each provides a fraction of the total pharmacy service. In some institutions drug distribution is provided by pharmacists from a central pharmacy, while consulting services are provided by "clinical" pharmacists on the floor. A certain pharmacist may spend the majority of his time in administration, or compounding solutions for parenteral administration, or reviewing drug profiles for drug interactions, or dispensing out-patient prescriptions, or providing drug information. A pharmacist who works on a pediatric ward may call himself a "pediatric pharmacist" to distinquish himself from the "psychiatric pharmacist" or the "internal medicine pharmacist," who is accustomed to working with different problems, caused by different diseases, and treated with different drugs.

We would like to make a few observations about this situation. First of all, most professionals have a tendency to find a unique name for themselves or the services they provide. This does not make them "specialists," and does not necessarily mean that their function must be continued by personnel with previous specialized training or experience. Resist the temptation to give every position a special title. Resist the temptation to departmentalize, especially at the beginning. The changing needs of patients and students can be met in the long run only by a flexible organizational structure or by an ever increasing budget.

Second, be sensitive to the problems that develop when specialized service personnel provide clinical training for general practitioners. A drug information specialist is best equipped to give specialty training. He is not the ideal role model for the student who intends to enter community practice. For the present, the general practitioner of pharmacy will not refer a patient to the specialist, the way his counterpart in medicine might. If he is expected to work within the confines of a general practice, and if he is being taught by someone who is considered a specialist in the host institution, a conscious and deliberate effort must be made to bridge the gap between what he observes in the role model and what he can ultimately do in his own practice. We do not imply that a specialist should not teach a general practitioner. We do think that we must take care establishing the relevance and practical application of some clinical training as we do for the basic sciences.

Finally, we come to the administrative structures that oversee professional and supporting services. Pharmacists who provide services in institutions generally report to a director of pharmacy services, who in turn reports to a hospital administrator. Members of the college faculty are generally responsible to the chairman of a department, and ultimately to a dean. Individuals who have both service and teaching functions, as all clinical instructors must, may find themselves with two bosses, or even worse, two individuals with identical functions may report to different supervisors.

Solving this problem, fortunately, is beyond the scope of this paper. From our (admittedly biased) point of view, the structures that work best are those where both service and education are a responsibility of the college, as in a contractual arrangement where the college provides service to a hospital for a fee. In any case, where differences in philosophy exist, the greatest influence is exerted by the administrator who hires, fires, and recommends salary increases. It may not be to your advantage to have the institution assume the entire salary of clinical personnel who teach there. You probably won't have enough money to keep all of the clinicians on salary, but you will gain the most if you pay those with administrative or supervisory roles.

We believe that all pharmacists who participate in training programs of the college should be given appointments on the faculty and be allowed to vote on matters brought before the faculty, whether they are paid by the college, part-time, or volunteers. Since this usually gives the greatest number of votes to new appointees with the least teaching experience, it frequently creates a threatening situation for the more established members of the faculty who teach the basic sciences. We have found these fears to be unwarranted. The sudden increase in size of the faculty is impetus for greater communication and compromise. There has also been a greater attempt to solve contentious issues in committee. In our situation, we have found that when a controversial issue must be resolved by the entire faculty, the clinical members of the faculty seldom vote as a block. I do not know anyone at our college who wants to retreat to the place where our practitioner-educators played a more limited part in decisions that effect the college.

Before we proceed to a discussion of some specific supporting services, let me summarize the recommendations for colleges with limited resources that are about to initiate clinical programs:

1. Base supporting services on an assessment of needs, giving highest priority to services that provide release time for clinical activities.
2. Many supporting services make excellent training sites for students, although the service rendered is not always typical of that found in general practice.
3. The college should attempt to provide partial funding for supporting services that play a major role in the instructional program.
4. Pharmacists that provide supporting services should be participants in the decision-making processes of the faculty.

Time does not permit us to discuss every supporting service that might be provided for a new clinical program. We will pass over those that are associated with the pharmacy services offered by most hospitals, and focus on a couple that usually do not surface until the institution becomes a site of clinical training for a college of pharmacy. The pharmacokinetics and drug information services are typical of those supportive services that are initiated by colleges, provide a clinical training site for students, and greatly expand the potential usefulness of the clinical pharmacist.

Pharmacokinetics laboratories determine the quantity of various drugs and their metabolites in body fluids. The pharmacist who operates the laboratory also provides consulting service, advising physicians and other pharmacists in matters relating to individualized dosage regimens that will elicit the desired therapeutic responses. This consulting service is most often required when response cannot be predicted from data collected from the normal population because of the effects of genetic characteristics of the patient, dialysis, disease processes, drug interactions, or product formulation on absorption, metabolism, and excretion of the drug. The service is also useful in devising treatment for drug overdosage and toxicity, and for determining the bioavilability of different products and dosage forms.

The data on pharmacokinetic services is limited, and most are relatively new, so we can only speculate about the place they will ultimately have in the treatment of patients. There are less than a dozen such services now in existence. So far as we know, none are self-supporting. Most do not limit themselves to clinical services, but are also heavily involved in the instruction of basic pharmaceutics, pharmacokinetics research, or both. Although we cannot substantiate our opinion, it appears that service for patients may not even be the prime function of many of these laboratories.

The pharmacokinetics service is valuable because the pharmacists who work in this area have expertise and experience which is not generally available to the other clinical pharmacists, and the time required to solve complex problems do not take this pharmacist from other patient care and instructional responsibilities. The laboratory has (or will devise) methods for quantitative determination of drugs in biological fluids which are not found in the normal pathology laboratory. The pharmacokinetics laboratory is also a means to another end. When pharmacokinetic data is needed for studies that extend beyond the needs of an individual patient, the pharmacokinetics laboratory circumvents the normal pathology laboratory charges to the patient for these services. Also, the clinical pharmacist may find it easier to initiate an order for the necessary tests from the pharmacy-operated laboratory.

In at least one instance, the pathology laboratory assumed responsibilty for routine drug analysis once a need had been demonstrated and the methodology was well established.[1] The pharmacokinetics service had access to the data generated by pathology and retained full responsibility for providing clinical pharmacokinetic guidance to physicians regarding the significance of the drug level and the design and adjustment of dosage regimen. While this approach minimizes duplication and reduces the possibility of conflict between the two services, it also postpones, perhaps indefinitely, the day when the pharmacokinetics laboratory can use a "fee for service" to become self-supporting.

We hesitate to recommend pharmacokinetics services to colleges that are starting clinical programs because of the great costs involved. When the State University of New York at Buffalo began its program, $50,000 was spent to equip the 600 square foot laboratory with chemicals, glassware, balances, and analytical instrumentation, and it was anticipated that double this amount would be spent by the end of the third year.[1] Salaries were paid to a director (an Associate Professor), a technician, a research assistant, and a secretary. In the first two years of operation, direct cost to the school exceeded $100,000 (excluding grant funding), and this figure did not include rent, or supplies and equipment that were transferred to the laboratory. This means that during the first two years of operation, the school donated an average of $91 per year for every bed in the hospital.[1]

Pharmacokinetics laboratories may need to be licensed by the state if they provide service for patients in addition to their research activities. This process is likely to produce some delicate negotiations, since health departments and other licensing agencies are not likely to have encountered similar services, and the standards for pathology laboratories may not be entirely appropriate for this unique situation. A special permit was created for the Clinical Pharmacokinetics Laboratory at Buffalo, but other states are likely to have a different solution for this problem.[1]

In summary, pharmacokinetics laboratories are both experimental and expensive to institute and maintain. Most appear to be supported by grants and are as heavily engaged in research as in service. While they provide excellent support for clinical pharmacy, the role of the pharmacokinetics laboratory as a training site is less certain. The relationship of the pharmacokinetics service to the pathology laboratory needs to be carefully defined, and the requirement for licensure must be satisfied.

When the clinical pharmacist appears on the medical unit, he establishes his credibility by providing accurate and useful information about drugs that is not readily available from other sources. Until he does this, he will be an observer, and not a participant. Every effective pharmacist deals in drug information.

The pharmacist must monitor drug therapy and make recommendations concerning the patient's total drug therapy. This requires that he be an expert on all of the information about drugs. Certainly this is a very formidable task. New information must be gathered and evaluated daily as new drugs and new methods of drug therapy are reported. To perform this task the clinical pharmacist needs available to him a service whose primary purpose is the ability to retrieve, evaluate, and disseminate information about drugs.

These activities are commonly provided by departments of hospitals or colleges called "drug information centers." These centers usually consist of a small specialized library containing journals, references, texts, in addition, to a number of secondary resources utilized to retrieve relevant articles from the literature. The second, and probably most important aspect of this resource, is the personnel who are responsible for providing the service. A pharmacist, who has a special interest, and often special training in the area of drug information retrieval, evaluation, and communication is required.

Why is this resource necessary? If the clinical pharmacist is going to be recognized as a drug therapy consultant first it will be necessary to gain the respect of physicians and other health practitioners. This can even occur without the pharmacist's presence in the patient care areas. It can occur within the confines of the traditional practice environment. The first step is to have a pharmacist who is willing and truly interested in performing this new service. Once that has occurred it will be necessary to provide the pharmacist with a modest library of journals, texts, and references so that he will be able to both remain current on the drug literature, and in addition, seek solutions to drug therapy dilemmas received from physicians and other health practitioners.

We believe that the practice of clinical pharmacy in this country has evolved, to a large extent, from drug information services, and this model can be repeated in the hospital to establish the validity of a pharmacist in a consultant role where drug therapy of individual patients is concerned.

The mere establishment of a library and pharmacist to respond to drug information inquiries does not mean that questions are going to come rolling into the center. The pharmacist must seek contact with the other members of the health care team. This can often be done by a variety of mechanisms: work on hospital pharmacy and therapeutics committees, newsletters, seminars, or personal visits, to name a few. The next step in the clinical involvement of the pharmacist is to place an individual in the patient care environment where he will be in close contact with physicians, patients, nurses, and other health care personnel. In this environment, the pharmacist will be more readily accessible by other health care practitioners to answer and help solve drug therapy problems. In addition, it will place the pharmacist in a position where he is better able to monitor the effects of drugs on patients. By going on patient rounds and reviewing charts this pharmacist will have the opportunity to detect side effects, inappropriate therapy and drug and laboratory interactions.

Being in this environment will usually increase the number of drug information inquiries received by the clinical pharmacist and, in addition, raise many questions in his own mind. If this individual is required to research the solutions to these problems it will necessarily detract from his involvement in the clinical area. In order for the pharmacist to perform these new functions it will require the availability of a support service to help solve the drug information problems posed to the clinical practitioner. Without this support service the activities of the clinical pharmacist in the patient care area will be severely inhibited. The clinical pharmacist cannot spend time away from patient care areas to retrieve and evaluate masses of drug literature any more than the physician can spend time away from the patient care areas performing his own laboratory and x-rays studies.

It is important for us to point out that the support services we are talking about does not necessarily have to be a special place or room within a hospital or college. A drug information center, per se, is not required. A service, is needed, not a space. The individual who provides the service may have other responsibilities in a college or hospital. The resources which are used by this practitioner may be in a hospital pharmacy, a hospital library, or a college library. The important thing is that pharmacy practitioners in the patient care areas have an individual they can consult with on their drug information problems. Ideally, of course, it would be desirable to have all of the journals, references, texts, and secondary sources used by the drug information practitioner in a single location in order to maximize the efficiency of that service.

Detailed information on the establishment and operation of drug information services can be found in the recent literature.[2-8] In this paper we will attempt to draw your attention to a very few aspects that we feel deserve special consideration.

Collins and Lazarus say that a drug information center can be established and operated for $25,000 to $35,000 per year,[2] a figure that is supported by our experiences at the University of Nebraska. The University of Alabama Hospitals and Clinics Drug Information Service had expenses of $29,400 for its first year of operation (1971).[3] Although the sky is the limit, especially for drug information centers that provide service for a large geographical region, instituting the service in a hospital does not cost much more than adding a scientist to the faculty and providing the space and auxiliary support that he would need for his activities.

Toll-free WATS long distance telephone lines enable a college-operated drug information center to serve all of the practitioners of the state, but the lines cost thousands of dollars, and are usually not provided in the absence of grant support. Some drug information centers encourage practitioners outside the immediate facilities to use their services, and others do not. There has been much discussion about a "fee for service" for responses to requests that originate outside the host institution, both to defray costs, and to discourage inquiries that could easily be handled by a local pharmacist using readily available references. Inside the institution that serves as a base for drug information service, the costs are absorbed by the hospital pharmacy or college, where they may eventually be passed on to the patient in the form of drug charges or hospital room charges.

The relationship of the drug information service (or any supporting service) to the pharmacy staff should be defined. Many think the request for information should be sent to the drug information service by the clinical pharmacist. This keeps the clinical pharmacist informed about the needs and problems that are occurring in the patient care area that he serves, and allows him to provide an immediate response when the inquiry is not complex enough to warrant referral to an outside drug information source. Others are less concerned about keeping the inquiry within a particular channel. Some method of determining priorities must be established, and, like any other pharmacy service, a written statement of policies and procedures should be prepared to guide those who may have less experience in this area.

At the University of Nebraska we were forced to choose between three possible locations. The drug information center could have been placed in the facilities of the College, in the Medical Center library, or adjacent to the central pharmacy at University Hospital. The hospital site was chosen because staff pharmacists there could receive requests for information and respond to some of these if the drug information pharmacist was out of his office. A hospital location allows the drug information pharmacist to have more frequent personal contact with the medical staff, and makes it possible to efficiently utilize the secretarial and clerical personnel shared with central pharmacy.

Incidentally, we believe that 24-hour service is very important. We don't think that pharmacists are likely to be held in high regard as long as a nurse is dispensing the drugs that are needed at night. A physician may need drug information at any hour of the day. We don't think his call should be answered by a librarian or a tape recorder. Since our drug information center is next to a central pharmacy with 24-hour service, there is always a pharmacist to respond.

A great many drug information centers keep complicated records and compile impressive statistics on the nature of requests received and the information provided. There must be a hundred papers that tell us what percent of the requests for information come from nurses, how many could be answered using the PDR, and what fraction were answered within the next hour. Some record keeping is essential for evaluation, but needless paperwork can make any position boring.

The Study Commission on Pharmacy reports that the number of drug information centers is falling, utilization of these centers by pharmacists and physicians is not as great as might be expected, and costs of $10 to $20 per question have been reported.[9] There does not seem to be any question about the value of drug information services, but we do not know if they will survive apart from colleges and teaching hospitals that can justify them on the basis of their value to the educational program.

I began this paper by telling you about the difficulty we had deciding what should be called a supporting service. My discussions with the members of our clinical staff did not make this decision any easier, but I did collect an interesting reaction I want to pass on to you in closing.

One member of our faculty thought that the most important supporting service was a strong central pharmacy. He does not believe that clinical consultations can easily be separated from drug distribution. The physician doesn't want advice from someone who can't get the drug to the floor when it is needed. Whether he likes it or not, when the drug distribution system is inefficient, the clinical pharmacist will share the blame.

This same clinician believes that one supporting service - clinical - pharmacology - may actually make it more difficult to initiate a clinical pharmacy program. He contends that, because they are competitors to some degree, good clinical programs thrive where the clinical pharmacology programs of the college of medicine are not well developed, whereas no outstanding clinical pharmacy service has emerged from a medical center with significant strength in clinical pharmacology.

I have enjoyed sharing my thoughts on supporting services with you and I appreciate your attention.

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# EVALUATION OF CLINICAL PHARMACY PROGRAMS

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## INTRODUCTION

The focus of attention at this International Congress has been on the clinical component of pharmacy education and practice. The speakers have examined the clinical pharmacy concept from a variety of viewpoints. By now it should be obvious that clinical pharmacy is actually composed of a variety of activities or functions which an be performed by pharmacists. Most of these are patient-specific, and center around the responses to drugs. Compared to the more traditional roles of pharmacy practice which emphasize the procurement, preparation, and distribution of drug products, clinical pharmacy activities are more labor-intensive. Thus, the number of pharmacists required to serve a specified population of patients is increased when clinical services are provided as compared to when only traditional pharmaceutical services are involved. The net result can be an apparent increase in the cost of providing the total pharmaceutical service. It is thus necessary to consider whether there are benefits to be accrued from the clinical services which make the cost increase worthwhile and/or act to achieve financial savings at some other point in the health care delivery process. Evaluation of the success or quality of a clinical pharmacy service may also be necessary in order to prove that there is an appropriate environment in which to teach pharmacy students the techniques of clinical practice. In the context of this presentation, the term evaluation is used in reference to conducting a set of experiments or observations which are designed to demonstrate and measure the various possible impacts of a clinical pharmacy service on the health care system in order to reach a judgment about its relative value or quality.

Although it may seem intuitively obvious that it is desirable to evaluate clinical pharmacy services, there has been very little activity in this respect since the inception of such programs in the mid to late 1960's. The few evaluations which have been performed have usually mixed clinical services with improved drug distribution systems. The results of these studies do not clearly identify benefits accrued from clinical services alone. The lack of evaluative research probably has resulted primarily from the complexity of the task. Most of the expected benefits of clinical pharmacy services are subtle and manifest themselves in ways which can be assessed only by subjective measurement techniques. There are a large number of variables other than clinical pharmacy roles which can act simultaneously on the patient care process and thus make it difficult to establish a controlled research environment. Evaluative research itself is also time consuming and costly.

The evaluation of a clinical pharmacy program must consider two components. The benefit in terms of quality of patient care, and the cost of providing the clinical pharmacy service. When the benefits have been measured and the costs determined, it becomes possible to make a cost-benefit analysis of the service. An opinion can then be developed concerning whether the benefits accrued from the clinical pharmacy service justify the cost.

An evaluation of a program may be done for one of two broad purposes. The first purpose would be to conduct an evaluation to certify or demonstrate the validity of a program. The second would be to conduct an evaluation to improve a program. The purpose is determined by the type of information needed by the individual or agency who must use the results of the evaluation. The evaluation for purposes of certification is done when one wishes to demonstrate or document the overall value or quality of the program.

Thus, certification evaluations appraise a program's overall quality or its impact and worth to society and certify it as being able to produce certain outcomes. Evaluation for certification is typically done on an established, functioning program. This type of evaluation might attempt to identify the extent to which program goals have been met, it might measure the impact of a program on a special group. Probably most important, certification evaluations usually compare the value of a program to various alternatives and examine its side effects in terms of its environment and demonstrate the consequences of the existence of the program. These evaluations usually view a program as part of a relatively large social structure and take into account all potential participants and comparable programs. They identify measure benefits and losses incurred as a result of the program and the overall impact on society.

Evaluations for purposes of improvement are typically done on programs which are developing or are in various stages of implementation, or on established programs when the environment has changed and hence, program adjustments may be needed. These evaluations focus on obtaining information about the internal dynamics of the program. Results of such evaluations are usually not useful for comparing the program with others or to establishing its importance within the larger framework of health care delivery.

This paper will consider general schemes for evaluation of a clinical pharmacy service from the standpoint of its impact on quality of patient care and on costs of delivery of care. Because such evaluations are complex and borrow on a wide variety of scientific disciplines, only a conceptual model for evaluation procedures will be presented. This presentation should be regarded as an outline which needs addition of much detail by the person wishing to embark upon a program of evaluative research.

## EVALUATING CLINICAL PHARMACY SERVICES

From the preceding section, it can be concluded that there are at least two general approaches which can be taken toward evaluating a clinical pharmacy service. The approach selected will depend upon the purpose of the evaluation.

One approach is to attempt to identify the beneficial effects of the total service provided by the clinical pharmacist on the delivery of health care to the patient. This would be the evaluation for certification discussed above. This approach is more global and allows one to arrive at the answer to the question, "Do the activities of the clinical pharmacist contribute in a significant way to improving the quality of health care in the patient population under study?" It has the disadvantage that it does not identify how each of the various component activities of the clinical pharmacist contribute to the patient care process. Thus, one cannot determine from such a study the efficiency of various activities of the clinical pharmacist and assign any type of cost benifit ratio to various components of the clinical pharmacy service.

The second approach is to attempt to analyze each individual task which makes up the clinical pharmacy service with respect to quantifying its impact on the drug therapy component of patient care. This approach relates more to the program improvement evaluation. It has the advantage that it does allow one to obtain definative information about whether or not a specified task of the clinical pharmacist is effective in improving patient care. The disadvantage of such an approach is that a study of the complete service is time consuming; frequently the differences in patient care caused by any one activity may be quite small and therefore, difficult to measure; and finally, it is difficult to separate the impact of one task from another in the practical working sense.

## Evaluating a Clinical Pharmacy Program for Purpose of Certification

At this point, I would like to define three terms that will be used in following discussions. These are *structure*, *process*, and *outcome*.* Structure relates to the physical components and people who make up a system of delivering health care. The structure of a clinical pharmacy service might include the clinical pharmacists, the equipment they utilize, their physical facilities, etc. The structure of the overall health care system includes the physical facilities, the equipment, the people--in this case physicians, nurses, pharmacists, dieticians, social workers, etc. Process is what the health care professionals do on behalf of the patient as they provide health care. The process component is the constellation of activities performed by all the health professionals on behalf of maintaining health. Finally, outcome, refers to the results of care, that is, patient response in terms of such factors as mortality, symptoms, ability to work or perform daily activities, effect on society, etc. To summarize, health care is composed of *structure*, that is, the system which provides the care; *process*, the actions performed by all persons involved; and *outcomes*, what happens as a result of the process and because of the structure. Both structure and process to a significant extent determine the outcomes.

The implementation of a clinical pharmacy service component which did not exist previously in a health care delivery system can be simply thought of as being an alteration in the structure component of the delivery of health care. It thus becomes a new variable affecting process and outcome. If the clinical pharmacy service can be isolated as the only "new" variable in a health care delivery system to a population of patients, it can be studied and evaluated by measuring any changes which occur in the process and the outcomes of health care in that population of patients. Once the changes which occur in process and outcome are identified, either quantitative measures or opinions can be developed concerning whether health care has been improved by introduction of the new variable--the clinical pharmacy service. To do this, the clinical pharmacy service the clinical pharmacy service is established and its structure described. The probable effects on the process and outcomes of health care are hypothesized, data are collected and analyzed, and decisions are made concerning the benefits. If parallel evaluations of changes in cost of delivering health care are made, a benefit-cost relationship can be established. The following sections discuss a step-wise procedure which one would follow in the evaluation process.

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*Writings by Donabedian, cited under References, present excellent discussion of these terms.

Measuring Benefits of the Clinical Pharmacy Service: The component steps of the evaluation process are shown in Table I. The major question to be answered is whether the introduction of the clinical pharmacy program or the collection of clinical roles is achieving significant benefits either with respect to the process or the outcomes of the delivery of health care to patient which justify the existence of the program.

TABLE I. STEPS IN EVALUATING THE IMPACT OF THE COMPLETE CLINICAL PHARMACY SERVICE-EDUCATION PROGRAM ON THE PROCESS AND OUTCOMES OF HEALTH CARE

Step 1: Identify the types of staff by discipline or expertise to be included on the evaluation team.

Step 2: Analyze the structure of the clinical pharmacy service-education program with respect to its completeness and maturity.

Step 3: Conduct a task analysis of the clinical pharmacy service-education program and determine the distribution of time between clinical services, drug distribution services, and teaching services.

Step 4: Predict how the clinical pharmacy service-education program may influence the process and the outcome of health care.

Step 5: Develop the evaluation protocol. This includes the following steps or decisions:

a. For each item in Step 3, define what are the "indicators" that might signify that the predicted change has occurred.

b. How can these indicators be measured?

c. Identify variables or environmental factors other than the clinical pharmacy service which may also be present and act to influence process and outcome of health care.

d. In views of items identified in step c, what are the controls that must be established?

e. Consider items a through d, and identify those items listed in Step 4 which are practical to include in the evaluation of the clinical pharmacy service.

f. Develop and validate experiment protocols appropriate to the methods to be employed in measuring the predicted changes in process and outcome.

Step 6: Collect the data according to the experiment protocols, and analyze the results for their significance.

Step 7: Reach decisions concerning the magnitude of the impact of clinical pharmacy services in terms of benefit to health care.

The first step is to assemble the "team" of persons who will do the evaluation. It is important to recognize that the procedures used in evaluating the roles of the clinical pharmacist will be derived primarily from research methodology of the social and behavioral sciences. These procedures are markedly different from those of the physical sciences with which most of us are familiar by virtue of our research training. The research methodology draws heavily from experimental psychology, anthropology, sociology, economics, business and management, and from public health and industrial engineering. Of course, the fields of pharmacy and medicine will become involved in the evaluation, particularly at the technical level of development of experiment protocols, audit procedures, and the like. Another "must" discipline for the evaluation team is statistics. It is important to recognize the need to have on the evaluation team persons who have backgrounds and expertise in the social and behavioral sciences and who are skillful in using the research techniques of these disciplines. It is the need to collect a staff of skilled evaluators with a variety of disciplines which frequently makes the conduct of evaluative research costly. In assembling the team, it is important to consider whether a specific research discipline would be needed throughout the study or only for a short period of time. In the latter case, it may be appropriate to resort to the use of consultants to the project to provide the needed expertise to get a small part of the evaluation done. On the other hand, where a discipline or expertise is needed throughout the study, this person must probably be retained as a full-time member of the evaluation team. The role of the pharmacist-administrator in these projects is to train or orient the evaluation team to the clinical pharmacy concept and to assist in defining the parameters to be observed during the evaluation process.

Step 2, of Table I, has as its purpose an assessment of the structure of the program to establish whether or not it is at a stage of maturity or development which qualifies for conducting a "certification" type of evaluation. The ideal is to evaluate a program where the facilities are in place, where the pharmacists are experienced professionals, competent in performing their clinical tasks, and where their activities are accepted and understood by their colleagues in the health care delivery ststem and by patients. If these, and related conditions, are not obtained, then the evaluation will be assessing a clinical pharmacy program which cannot help but be only partially effective. Under such circumstances, the outcome of the evaluation may show no benefit when significant benefit could have been demonstrated if the pharmacy service had been allowed to mature to its fullest potential. Time does not permit a detailed discussion of how Step 2 may be carried out. In general, one could compare the clinical pharmacy service-teaching program to those which exist in other settings. These comparisons would be made with respect to degree qualifications of staff, activities performed by pharmacists, physical facilities, setting in which the service is provided, etc. Attitudinal surveys of other health professionals and patients could establish the degree of acceptance of the pharmacists performing the clinical tasks. Accomplishing Step 2 may be a formidable task. On the other hand, the maturity and completeness of the program may be self-evident, or may be assumed to be sufficient, for the evaluation to be conducted. In such event, Step 2 can be easily accomplished. It must also be remembered that virtually every program will continue to improve through self-refinement and increasing experience of the practitioners. Such improvement can cause drifts in base line data collected during the initial course of the evaluation.

The third step, conducting a task analysis, is needed for two purposes. First, in many pharmacy programs the clinical roles of the pharmacist are mixed in with more traditional activities such as management of the drug distribution system, formulation of drug products, procurement of stock, etc. Some clinical pharmacy programs devote considerable amounts of time to teaching students. If one is trying to isolate the cost-benefit relationships of the clinical roles of the pharmacist, then the time distribution spent among various activities must be known. The second purpose of the task analysis is to actually identify those actions of the pharmacist which comprise the "clinical" component of the service. Procedures to conduct task analysis are well known in the administrative sciences, and it is assumed that the evaluation team would contain persons with the expertise to develop these. Again, it is emphasized that the task analysis should not be done until the maturity of the service has been established.

Steps 2 and 3 are intended to characterize the clinical pharmacy component of the service models to be evaluated. Next, it is necessary to follow a series of steps which relate to the design of the experiments to be conducted. As the first step in this sequence, one must predict how the program may be expected to influence the process and/or outcome of the delivery of health care. Recall that the clinical pharmacy service can be thought of as an alteration in the structure of the health care delivery system; and if other variables can be isolated, any change in either the process of the outcome of health care can be attributed to presence of the clinical pharmacy service. In this case we are considering the impact of the pharmacy service on how health care is delivered to a patient population and how the status of health of that population may be altered. Table II shows some typical items which might be listed as being possible effects of the presence of a clinical pharmacy service on the process and outcome of health care.

## TABLE II. SOME POSSIBLE EFFECTS OF CLINICAL PHARMACY SERVICES*

### Effects on Process of Health Care

1. Reduced frequency of prescribing of contraindicated drugs by physicians.
2. Increase in rate of prospective detection of contraindicated drug combination.
3. Increase in frequency of selection of "drug of choice" by physician.
4. Decreased rate of self-administration error of drugs by patients.

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*Items listed in this table are intended as examples of possible effects of clinical pharmacy services on the processes and outcomes of health care. This is not intended to be a complete list, and it is probable that additional items may be added to both the process and outcome categories depending upon the type of clinical pharmacy service being evaluated.

Outcome of Care

1. Decreased morbidity in patient population.
2. Increased percentage of patients in therapeutic control in patient population.
3. Reduction in the cost of the treatment component of health care delivery.
4. Reduced rate of re-hospitalization attributable to or potentially affected by drug therapy considerations.
5. Better utilization of health manpower and increased access to appropriate types of health care by the patients.
6. Decrease in expenditures for health care among the patient population.
7. Decrease in the incidence and intensity of iatrongenic disease.

The next step is to develop the evaluation protocol. This would be done primarily by the team of evaluators assembled to conduct the experiment. Step 5, Table I, identifies some of the considerations which would be part of this process. It is first necessary to identify what are the "indicators" which would signify that the hypothesized effects on the processes or outcomes identified in Step 4 have indeed occurred. This is necessary in order to identify the types of observations that must be made during the data collection phase of the evaluation. This might include such items as changes in adverse drug reaction rates, average length of stay in hospital, quantity and rate of drug utilization by patients, cost of drug treatment, etc.

Once these indicators have been identified, consideration must be given to how they may be measured. The method of measuring the indicators must be decided by the evaluation group and it is impossible to discuss these at the present time in any comprehensive fashion. A considerable literature has developed in recent years concerning experimental methods to evaluate both process and outcome of health care, and some of these could be adapted to the evaluation of the clinical pharmacy service if we hypothesize that the service will be influencing both process and outcomes of the delivery of health care. One experimental approach may often measure several of the indicators that have been identified as probable results of the clinical pharmacy service. The list of References provides a starting point for further reading concerning measurement methods.

The third consideration in developing the evaluation protocol is to identify what might be the variables, other than the presence of the clinical pharmacy service, which may also be operating to influence the indicators to be measured as part of the evaluation process. There are usually many of these and it is in this aspect that the evaluation of the impact of clinical pharmacy services becomes most difficult. While the list of such variables is almost endless, following are two typical examples. In a teaching hospital environment, the physician staff is usually highly mobile. During the evaluation the physician staff working with the "study" service may change several times. Under such circumstances, it may be difficult to document improvement in the clinical use of drugs by physicians which results from their interaction with clinical pharmacy service. Another problem in teaching hospitals is that highly sophisticated medical experts are usually present. Evaluating the impact of a clinical pharmacy service on the use of drugs by such experts may reveal little beneficial outcome. However, if the study is conducted with non-university based physicians, who are usually much less expert in their use of drug therapy, the same clinical pharmacy service might be found to be highly beneficial.

Next, an attempt must be made to select suitable controls for the experiments so that the influence of the variables not related to the clinical pharmacy service can be cancelled or at least quantitated as part of the results of the experiment. The types of controls used may take many forms and, again, must be determined by the team of evaluators. One general approach of controlling an experiment is to evaluate the appropriate group of indicators in two very similar populations of patients; one of which is served by the clinical pharmacist, the other by traditional pharmacy services. This allows the cancelling out of a wide variety of variables which may influence the experiments. It does require that the "initial" structure and process of delivery of health care to the two populations is identical and that the characteristics of the populations which influence health care are also identical. These are not easy to achieve in the actual working situation.

Another general approach to controlling an experiment is to conduct a pretest period where the indicators are measured in a population of patients before introduction of the clinical pharmacy service. The same measurements are repeated after the service has become operational and has reached maturity. Any change observed in the indicators is attributed to the presence of the clinical pharmacy service. These types of controls have the advantage of "standardizing" the patient population and the general environment and structure of the health care delivery system. On the other hand, they are subject to a host of time-related variables.

Once items 5-a. through 5-d. of Table I have been considered, the evaluation team will usually select those items listed in Step 4 which are actually practical to include in the evaluation study. It may well be that not all of the items originally identified in Step 4 will be measured. The reason for this is that some of the indicators may be either impossible to measure or may be too expensive or time consuming with respect to the experimental methodology.

Once the basic experiment has been selected, the purpose of other steps in Table I is self-evident. It is important that, insofar as is possible, monetary values be assigned to each benefit identified by the experiment. This facilitates comparisons between benefits and costs. For example, if one benefit of a clinical pharmacy program is revealed to be a shorter length of hospital stay, an economic value can be assigned by relating the magnitude of the change in days to the average cost of a patient day in the hospital. Other benefits may be similarly equated to monetary values. However, it may not be possible to do this for all benefits that are realized. This is especially true where the specific benefit cannot be quantified and is therefore expressed in subjective terms.

Measuring Costs of the Clinical Pharmacy Service: A cost analysis of the clinical pharmacy program can be conducted simultaneous to the evaluation of the impact of the service on patient care. This should include both the direct costs of the service and the operating overhead or indirect costs. If the pharmacy service being evaluated provides a mixture of services as identified by the task analysis, then the component of the cost ascribed to the presence of the clinical pharmacy service can be determined from that percentage of the total activity of the pharmacist which is devoted to clinical as opposed to teaching and to drug distribution activities.

Time does not permit a detailed discussion of how costs may be estimated, but again the evaluation team should include persons of the appropriate expertise to perform these studies. The procedures are relatively straight foward and known to persons in the economic sciences. It is important to keep in mind that there will be two types of costs associated with the clinical pharmacy service. One will be the "start up" costs which relate to expenses incurred in establishing the service. These would include purchasing the necessary equipment, renovating space, recruiting staff, and the like. These are quite different from the day-to-day operating costs once the service is established. The "start up" costs should be separated from the cost-benefit analysis of the clinical pharmacy service. If one wishes to include the "start up" costs into the assessment of benefit versus cost of the service, it would be best to amortize these costs over a period of years. Otherwise, the apparent cost of the clinical pharmacy service may be judged too great in terms of benefits incurred.

Cost-Benefit Assessment: Once the benefit studies have been performed and the costs analyzed, it is necessary to reach a decision whether the benefits of the program are justified in terms of its cost. There are virtually no standards for making this assessment because of the paucity of available information concerning cost-benefit studies of clinical pharmacy services. Decisions would have to be based on priorities of the institution relative to the resources which are available to provide health care. What is determined to be an acceptable cost-benefit ratio by one institution or group of persons may very well not be acceptable in another setting. The cost-benefit relationships may strongly be influenced by the general structure of the health care delivery system, as well as societal needs and resources. In a society with an already well developed health care system, the initiation of a clinical pharmacy service may seem to achieve little additional benefit in relationship to the resources required. Whereas, in a society with a poorly developed or partially deficient health care system, the benefit that can be accrued from a clinical pharmacy service, particularly one that addressed deficiency areas in health care, might be very great in relationship to the cost.

## Evaluating a Clinical Pharmacy Program for Purpose of Improvement

Let us now return briefly to the matter of evaluating a clinical pharmacy service for purposes of program improvement. Such evaluations might be done during the initial stages of developing the service or as part of an attempt to further refine and improve the quality of service if the results of a certification-type evaluation have been favorable. Following remarks relate to this latter context.

In contrast to the evaluation for certification, where the attempt was to identify the impact of the total clinical pharmacy service on health care delivery, the improvement evaluation identifies whether specific tasks which the clinical pharmacists perform are contributing positively to the patient care process and whether they are achieving what is intended. This type of evaluation provides us with the information we need either to continue, to discontinue, or to modify a specific task being performed by the pharmacist as part of his overall service responsibility. The approach to the evaluation is similar to the scheme outlined in Table I. The same concepts of structure, process, and outcome apply. From the task analysis one identifies tasks or activities performed by the clinical pharmacist. For each of these, one or more results can be hypothesized. Next, indicators of the results are predicted and subsequently, experiments are designed to measure these indicators. Table III illustrates this process.

TABLE III. SOME CLINICAL PHARMACIST ACTIVITIES; POSSIBLE OUTCOMES AND INDICATORS

| Activity Category | Some Possible Outcomes | Some Indicators* |
|---|---|---|
| DEVELOPS DRUG USE HISTORY FOR INDIVIDUAL PATIENTS: | May identify medical complaint as being drug induced.<br>May identify history of allergic or idosyncratic reaction to drugs.<br>May avoid prescribing contraindicated drugs or incompatible combinations of drugs.<br>May identify patient specific factors influencing drug disposition. | Incidence of drug induced problems documented in the medical chart is increased.<br>Frequency of prescribing interacting combinations of contraindicated drugs is reduced.<br>Increase in rate of identification of patient specific factors influencing drug disposition. |
| MONITORS ALL DRUG ORDERS & RE-ORDERS: | May prevent prescribing interacting combinations of drugs.<br>May prevent administration of contraindicated drugs.<br>May prevent dosage errors.<br>May detect situations of misuse or abuse. | The rate of prospective versus retrospective detection of contraindicated or incompatible drugs is increased.<br>The rate of prospective versus retrospective detection of drug misuse is increased. |
| PROVIDES DRUG INFORMATION TO HEALTH CARE PROVIDERS: | Most appropriate drug is used in therapy.<br>Drug therapy related problems are identified and avoided or eliminated.<br>Appropriate dosing procedures are employed.<br>May reduce frequency of overprescribing of drugs by M.D. | Drug of choice is used more frequently and dosing procedures are correct.<br>Appropriate monitoring parameters are employed.<br>Amount of drugs prescribed (ordered) is reduced. |

| | | |
|---|---|---|
| MONITORS CLINICAL OUTCOME OF DRUG THERAPY: | Early detection of therapeutic failure.<br>Early detection of drug adverse reaction.<br>Early detection of need for change drug therapy program necessitated by patient's therapeutic status.<br>Improved therapeutic response or control of symptoms. | Increased frequency of change to "more appropriate" therapy.<br>Increased incidence of documented drug adversities, but a lower rate of morbidity and mortality resulting from adversities.<br>A greater percentage of patient population is in therapeutic control with fewer side effects and toxic manifestations. |
| PROVIDES DRUG INFORMATION AND CONSULTATION TO PATIENTS: | Patient compliance is improved.<br>Dosage administration errors by patients are reduced.<br>Medication misuse avoided or reduced. | Quantity and rate of drugs used consistent with prescription directions.<br>Patient understanding and ability to describe self-administration protocol improved.<br>Lower incidence of improper self-medication with non-prescription products. |

* Changes are relative to a control patient population not served by the clinical pharmacists.

Please note that Table III is not all-inclusive of clinical pharmacists' activities and is presented for purposes of example only. Note that the items listed in Table III are more "microscopic" in nature and do not always relate as directly to the process/outcome aspects of the total health care system as did those considered in the discussions about evaluation for certification. Note that some of the results are subject to objective-type measurements, whereas others can be assessed only by subjective means. Research methods can be designed for the various indicators and can be so specific as to isolate the contribution of a specific activity and to demonstrate whether it does or does not contribute positively to the expected result. Few of the results and/or indicators, by themselves, would provide proof that the outcome of patient care is positively effected. It should be noted that the experimental methodology for evaluating these results is complex and requires the expertise of scientists from a wide array of disciplines. Evaluation of a total clinical pharmacy service by analysis of specific tasks in this fashion is, in many respects, more time consuming and tedious than is the evaluation designed for certification. This is primarily a result of the large number of specific items which must be individually studied and evaluated. Thus, such an analysis would be more useful to refining and/or developing the service than to answering questions concerning the total impact of the service on the health and welfare of the population served.

## SUMMARY AND CONCLUSIONS

### Is Evaluation of the Clinical Pharmacy Service Necessary?

It should be obvious by now that evaluative studies of clinical pharmacy services are not only complex, but they are also costly and time consuming. A large staff for the evaluation team which includes persons from a wide variety of disciplines must be assembled. Sophisticated methods must be employed for collecting and interpreting data. Frequently, the studies must be carried longitudinally over a considerable period of time in order to capture enough events so as to be able to achieve statistical significance of observed differences as compared to controls. In view of the time and expense required to conduct these studies, it is logical to question whether the studies themselves are cost-effective in terms of the future of the clinical pharmacy program. Will there be sufficient positive outcome from the availability of such information to make these studies worthwhile?

On one hand, further development of clinical pharmacy service programs may be largely dependent upon our ability to demonstrate that we are achieving a significant degree of societal benefit to justify the costs of the service. This is especially true in the present time when costs of delivery of health care are rapidly increasing to the point where they are severely stressing society's ability to provide them. From this standpoint, sound evidence that clinical pharmacy services reduce the overall cost of health care or at least produce sufficient benefits to make increased costs worthwhile may be needed to guarantee our place in the health care delivery systems of the future.

On the other hand, there is growing inclination of pharmacists to provide clinical services. Our schools are producing graduates who are better and better educated and are interested in providing clinical services. In addition, there is considerable evidence to suggest that acceptance and reliance upon clinical pharmacy services by other health care professions is continually growing. Clinical pharmacy services may very well evolve into being considered a necessary component of the health care delivery system, regardless of a lack of data which rigorously demonstrates cost-effectiveness. This evolution may very well be facilitated by the continuing publication of research studies which attempt to evaluate the impact of specific clinical activities, e.g., patient counselling and medication records, on the process or outcome of health care delivery. A very rapid transformation is occurring in our health care delivery system. In this country we are faced with the impending adoption of national health insurance programs. Even now, third party providers of health care and the States are making decisions concerning the types of pharmaceutical services for which they are willing to provide reimbursement. It is entirely possible that before a rigorous study can be conducted, many of the decisions relative to clinical pharmacy's future will have already been made. These decisions apparently will have to be made on the basis of partial and rather incomplete information about benefits of clinical pharmacy service. Another matter which challenges the advisability of conducting the rigorous cost-benefit analysis relates to the fact that such studies are specific to the service being evaluated and to the environmental and social variables acting on the population served. Transferability of results may not always be easy for a variety of factors. I will not attempt to presnet a personal opinion whether it is appropriate or valuable at this point in time to establish and conduct rigorous reviews of clinical pharmacy services, particularly those aimed at the certification type study. I feel this must be reserved for consideration in light of the individual situation and factors associated with the relative urgency of need for the results of the evaluation. It is clear however that there is a need to consider the matter of whether there is sufficient benefit to be gained from the evaluation study to make it worthwhile.

## Conclusion

I have discussed evaluation of clinical pharmacy services from a conceptual viewpoint. I have tried to convey the point that the evaluation procedures are complex and will vary depending upon the intended use of the results. It is important to realize that evaluation procedures require a team of investigators, including persons from the social and behavioral sciences. Evaluations frequently must be done on a "mixed" type of pharmacy service that may include some clinical roles and some traditional roles, as well as teaching. To analyze specifically for the benefit of the clinical function requires a task identification. Lastly, the decision regarding whether benefits incurred by the program are justified in terms of cost must be made in consideration of factors which are unique to, and are operating in, the environment of the study. These considerations may very well be influenced by national health policy, availability of resources, and the general social and economic status of the population to be served more than by the absolute magnitude of the contribution identified to be a result of the clinical pharmacy service.

At the end of this article I have cited some selected references for additional reading. These are not intended to be an exhaustive compilation of the literature, but instead, are intended to provide a start for the interested individual.

## Acknowledgement

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# THE SOCIAL PHARMACY CONNECTION

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The pharmacist needs to know much more about the patient he serves. A case in point is that of a male dialysis patient: "Besides being on a no-salt and fluid-restricted diet, I am also allowed very little protein because the breakdown of protein creates waste products in the blood. I can eat only one egg, one ounce of cheese and six ounces of meat, fish or poultry a day.

Enough of restrictions? Not quite. I am also on a low potassium diet because I can get rid of potassium only while dialyzing and too much potassium in the system does something unfortunate: It stops your heart. So good-bye to orange juice, bananas, melons, peaches, apricots, nuts, chocolate, dark green vegetables, dried fruits, split peas, beans, and a host of other foods. The amount of raw fruit of any kind I can eat is limited. Ditto salad greens and vegetables. And the vegetables I eat at home are cooked in lots of water and then drained to leach out some of the potassium. Salad greens and potatoes are soaked for days in a large container of water, which is changed periodically, for this also eliminates some potassium. Do I cheat on my diet? Of course I do, being only human. But I know how to cheat cautiously and creatively. Hardest of all to resist is taking a good long drink whenever I want to. I am tired of little sips of this and that. I would give a year of my life to be able to chug-a-lug a huge schooner of cold, foaming draft beer, to feel it rush down my parched throat like a flash flood through a desert ravine. I would give another year to slug down an ice cream soda in two huge gulps. And a third year for a whole pitcher of ice water, beaded with little drops of condensation on the outside, cool, crystal clear and a half-gallon deep within. Dialysis patients take lots of pills; I gulp down eight every morning, five at lunch, five at dinner and three before I go to bed. But life goes on and I am happy to be living with all its restrictions. We have found ways to cope."[1]

The program on "Clinical Pharmacy Education: How To Do It," should go far toward helping pharmacy educators think about the experiences and lessons of others and their potential application in their own respective settings. One area though, has been absent thus far as a subject in the deliberations of this Congress. And it is indeed a most important area. It is the material that is sometimes referred to as Social Pharmacy or Pharmacy Administration. I hope to justify and document that claim and convert you to be an advocate for greater instructional emphasis on the social pharmacy area. Lastly, if I am successful and have won you over, I must not leave you alone, and therefore will provide some direction for further efforts by the inclusion of a list of suggested readings and of outlines of areas that must be included in the education of a pharmacy practitioners in the realm of the social, behavioral and administrative sciences.

But first to the problems. We must identify problems prior to designing solutions to overcome the problems. Possibly, a statement by Ivan Illich says it all: "In the United States, 20,000 tons of aspirin are consumed per year, almost 225 tablets per person. In England, every tenth night of sleep is induced by a hypnotic drug and 19 percent of women and 9 percent of men take a prescribed tranquilizer during any one year...Dependence on prescribed tranquilizers has risen by 290 percent since 1962, a period during which the per capita consumption of liquor rose by only 23 percent and the estimated consumption of illegal opiates by about 50 percent..."[2]

It is surely not necessary to recall before this group the abundance of reports in the published literature citing drug induced disease, drug interactions, less than optimal use of drugs such as psychotherapeutic agents and antibiotics. In brief, there is room for improvement in the usage of therapeutics. Knowledge of this fact is insufficient to forge change, but is a good first step.

While it is useful to have some knowledge of pharmacology and medicinal chemistry, neither of these disciplines alone provides the basis for adequate competence for a practitioner. Such is also the case with the inclusion of aspects of the social and behavioral sciences within the pharmacy curriculum. The area can provide a great deal of good for the pharmacy student and his or her future patients, but surely not everything the future practitioner must learn about the world around him or her. Let us pause though and focus on the subject. Broadly speaking, the social and behavioral courses would include nearly everything other than the physical and biological sciences. This could then include law, business administration, psychology, sociology, economics, public health, anthropology, political science and a long list of other non-laboratory sciences.

Fortunately, no one is suggesting that the pharmacy student must be "subjected" to a course (or courses) in each of these fields, but it is proposed that relevant information and concepts from many of the aforementioned fields can be incorporated into the curriculum where appropriate. When the student studies the pharmacology or dispensing of narcotic agents, for example, the student should then learn about the pertinent law and also about the more important history of that class of drugs which led to the necessity of the rather strict present laws. At this point, it may or may not be appropriate to discuss the social uses of drugs or deal with the topic of drug abuse. This then is an example of how the social and behavioral sciences are playing an increasingly more important role in contemporary pharmacy education.

There is a caveat however. Any advocate of the inclusion of social and behavioral science subject matter into the professional curriculum must be totally candid and acknowledge several points. For one thing, we simply do not as yet, know the cost-benefit ramifications. Many of us suspect that we are arming future pharmacists with increased ability to deal with patients, health-care providers and colleagues, and arming them with increased insight into the organization, functioning and development of the health-care delivery system. Still we cannot say with assurance that resources devoted to this area will have a specific payoff. While no other branch of the pharmaceutical sciences can offer such evidence, that should be little justification for the pioneers working in this area.

There is another caveat as well. Despite the enormous enthusiasm of many of us, we must admit that the application of the social and behavioral sciences to pharmacy education is not a panacea by any stretch of the imagination. In fact, harm can come to all involved if the expectations accorded the area are not realistic. The area has the promise of doing many things, is unable to accomplish many others; and may aid in the success of other goals in conjunction with other inputs. If unreasonable or unattainable expectations are generated, more harm than good will be produced.

Our colleagues are recognizing the undeniable fact that clinical pharmacy is taking hold and with it, there is a need for the pharmacist to be able to deal with patients and health professions practitioners. This pharmacist will be obliged to learn about the drug-use process and about the origins, hurdles, trends and lessons gained from professional experience and experimentation. The pharmacist will be required to understand interpersonal relations, group dynamics and organization theory in order to successfully work with or through contemporary institutions. Precious resources must be managed rationally or else they will be lost. Certain behavioral modifications must be effected and young pharmacists are the ideal candidates for agents of change. Pharmacists must venture out from their prescription counters and meet the public, since the public's ignorance of pharmacists and of the full range of pharmacy services only breeds mistrust, suspicion and an artificially maintained barrier to conversation.

All of the knowledge of pathology, pharmacology and the other clinical sciences is useless unless the pharmacist can effectively communicate with physicians, nurses and patients. And of course, social and behavioral skills are hollow if the pharmacy practitioner does not have the ability to make accurate clinical therapeutics judgements. So then, the social and behavioral sciences go hand-in-hand with the evolving patient orientation in pharmacy practice. Today, pharmacy students at about a dozen colleges are routinely exposed to instruction dealing with diverse aspects within this umbrella that include: dealing with death and dying, dealing with patients and the family of a terminally ill patient, understanding the basis for the use of the placebo, understanding correlates of patient compliance with prescribed therapy, the lay referral system, illness behavior, the sick role, cultural differences in reaction to pain and illness, risk-taking behavior and self-medication, stigma, patient rights, the effects of treatment environments and expectations, theories in psychosomatic medicine, client control, and many other concepts, topics and issues.

As may be seen, what is proposed is a culling, from the rather massive literature in the social and behavioral sciences, those concepts which apply to anticipated and present pharmacy practice. Then the difficult work begins as the material must be integrated in a meaningful way into the pharmacy curriculum. There can be no formula for this phase of the chore as individual effort is required to custom tailor material into the needs, situation, resources, location, of each college of pharmacy.

An exposure to selected teaching in the social and behavioral sciences cannot create miracles, but it can go a long way toward preparing pharmacy graduates for their expected future roles. By understanding non-verbal communications, patient anxiety, and the fabric of the health-care delivery system, the pharmacist should be better able to deal with those everyday problems that are so important to patients. An understanding of what the patient is going through during times of stress or grief, for example, can aid the pharmacist in providing more than just drugs to the patients who depend on her or him. The ever-present drawback is that such offerings require resources of a magnitude somewhat greater than those employed in a traditional lecture course. A competent instructor must be located and (as is always the case with newer fields of study) there are always too few qualified people available. Even after that problem is solved, such a course or (hopefully) series of courses will require an enormous expenditure of resources and effort to mount a successful endeavor. Arrangements need to be made with local social service agencies caring for the chronically ill, the disfigured, the elderly, the poor and others, so that pharmacy students may observe first-hand the care of (and reactions toward) these people and then discuss actual cases with human services personnel.

Events of the day must be translated into impact-on-pharmacy terms. What all of this requires is a genuine commitment on the part of the college of pharmacy to the goals held by those advocating the inclusion of behavioral and social sciences into pharmacy education. That means financial support; it also means cooperation in making the curriculum flexible to accomodate course offerings early in the program and throughout the program. For all those costs and inconveniences, only a few things may be promised in return. Surely, such course offerings will produce a more well-rounded practitioner - but beyond this, the other payoffs are speculative or hoped for and without the weight of scientific evidence as would be seen in a statistically valid double-blind study. Students exposed to these concepts should develop into more compassionate, whole-patient-oriented practitioners - able and confident in dealing directly with their patients and other health-care deliverers.

While we cannot quantify the payoffs in a cost-benefit equation at present, many of us are certain that ignorance of the area is a greater cost, greater risk path which we cannot afford to follow.

Moreover, the traditional courses offered in Colleges of Pharmacy, such as pharmacognosy, have never been subjected to such relevance and value tests either, and their presence in the curricula surely dates back 100 years already.

The social sciences have applicability to all undergraduate students regardless of their practice objectives. All graduates will be working in organizations which, if past trends continue, will become larger and more complex. To function effectively in these organizations, today's graduates must have an understanding of human behavior in organizations and procedures employed for optimizing the effectiveness of physical and financial resources. Without this, it is unlikely that pharmacy can maintain control over its practice. Medicine and dentistry also realize this because of the increased emphasis on administration in family practice programs in medicine and on the administrative aspects of dental practice.

Equally significant without this orientation pharmacists will not be able to assume new roles which pharmacy educators consider necessary.

One of today's greatest challenges is to provide pharmacists with sufficient tools so they can market their new roles so effectively, that society and other practitioners will accept these roles and reward them accordingly. The success of incorporating these roles into the practice routine requires not only an understanding of pharmaceutical marketing and the health care system, but also an understanding of efficient utilization of human and financial resources in achieving these functions, because increasing demands for health care services will force efficiency in their delivery by all health manpower.

Human behavior is the product of a person's cognitive and affective attributes and the environment in which he exists. Social psychology has developed an integrated theory base which relates the variability of the qualities of individuals to the variability of social environment, a most appropriate perspective for developing a complete behavioral scientist in pharmacy. To be competent in designing and analyzing data obtained from experiments concerned with investigating human behavior processes, a pharmacy graduate student should have an extensive grounding in social science research methods, including parametric and nonparametric statistics, experimental design, and psychometric scaling theory and techniques, with a particular emphasis on personality and attitudes.

The social sciences in pharmacy area should include three major categories of knowledge: (i) health professionals, with particular emphasis on the professional behaviors of pharmacists and physicians, (ii) the health care user, with attention directed toward health and illness behaviors and their relationships to drug obtainment and utilization and (iii) health care organizations and social institutions, particularly law, politics and economics and their effect upon the behaviors of health professionals and patients in relation to restorative or rehabilitative care. Approximately 40 percent of the knowledge required for expertise in the social sciences in pharmacy can be obtained through undergraduate courses dealing with drug marketing, pharmaceutical law and socio-economic aspects of pharmacy practice. An integrated sequence of these courses should consider the basic social and economic factors which affect pharmacy as a system of social behavior.

Social Pharmacy and Clinical Pharmacy are natural partners, but unfortunately, this is not a universally recognized fact. The statement is not disputed by persons who have thought about the topic, but it is not even thought about by far too many pharmacists and educators. As noted previously, interest in administrative knowledge is being recognized by medical and dental education programs at a time when pharmacy, with a history of acknowledged need for administrative knowledge, seeks to polarize its clinical interests. Basic to the understanding of this partnership between the two areas is the fact that social pharmacy subject matter is oriented toward the administrative and social sciences and not toward the commercial trade functions oftentimes cited.

There are many categories of knowledge and skill by which the two disciplines can engage in productive activities. These can be cited as follows: knowledge of the health care system, practice management, documentation of services, operations research, electronic data processing, research methodology, planning and problem solving.

Meredith Wilson's advice that "you have to know the territory," is no less important in health care delivery. The clinical pharmacist can learn from social pharmacy who all of the players are, how they fit together, and what can be expected from different people. Knowledge of past experiments, foreign organizational schemes and alternative practice arrangements in organization and financing can be of significant value. An understanding of the history and development of the present health care delivery system can prevent repetition of costly errors and the "reinvention of the wheel."

Even the most pure, theoretical experiment or sophisticated surgical procedure has someone recording costs and expenses, and although the clinical practitioner may think that commercial aspects are beneath his dignity, he soon comes to realize he must establish a firm, economic base for his practice. Clinical pharmacists should learn about break-even analyses and budgeting. The most valuable asset of the clinical pharmacist is time, a resource in short supply which must be managed and regulated. There can be no escaping the fact that the clinical pharmacist must generate a livelihood.

The hospital or clinic has scarce resources which it hopes to use in a combination to obtain an optimal return in quality and quantity of services rendered. Social Pharmacy can lend the skills necessary to measure changes in efficiency and productivity and to undertake task-analysis and work-sampling programs to aid in scheduling an optimal mix of inputs. Other management functions which pharmacy administration can offer to the clinical pharmacist lie in the areas of systems-implementation. System models may be created to aid in working with inventory, personnel scheduling, and other important but routine activities.

Most performance units in a system require documentation of services to measure against standards of accountability and productivity. The clinical pharmacist may know countless techniques and programs to provide any number of services, but he will eventually be confronted by the hospital administrator who will ask about the values to be gained from implementing one of these clinical services. The clinical pharmacist must understand the basic element of evaluative research so that he or she may establish demonstrations and experiments to document the cost-benefit of cost-effectiveness of the services proposed. The Social Pharmacy area can aid the clinical phramacist in research designing and statistical analysis.

Countless questions/problems may be answered/solved through creation of research projects to obtain further data. There are right and wrong means to collect valid and reliable data, and social pharmacy can contribute to clinical pharmacy's needs in this realm. There is much to be gained from the optimizing of services rendered by clinical pharmacists in the establishment of systems and protocols or routines. The application of operations-research type studies should aid in the development of more efficient and productive clinical pharmacy services. The use of forms and the modification of task sequences can many times aid service output.

Social Pharmacy instruction should be able to demonstrate immediate and tangible benefits for clinical pharmacy in the areas of planning and problem solving. The basic principles of defining the problem, posing alternatives and selecting a best solution can be supported by instruction in planning practices. Critical Path Method (CPM) analysis, Program Evaluation and Review Technique (PERT) methodologies and Planning-Programming-Budgeting System(PPB) schemes are powerful tools to facilitate planning and control of complex programs, and they should be of value to clinical practice personnel for scheduling and resource allocation decisions.

Social Pharmacy personnel should be able to assist the clinical pharmacist in the establishment of management information systems, and with the development of data processing applications, tailor them to the specific needs of a clinical pharmacy service group. Dosage scheduling, interaction reports, billing and updating of integrated records are now commonly processed, using computers. Included in this area is the adoption of procedures and forms to accomodate use of the problem-oriented medical record.

The development of programs should concentrate on the strengths in a given school and university system and become oriented primarily to the needs and objectives at each site. Instruction in both of these areas should be coordinated with or integrated into social and clinical pharmacy instruction at undergraduate, professional and graduate degree levels, to provide advanced programs which uniquely prepare students for particular positions in pharmacy, health care, or government service.

To provide expert instruction, cooperative research and better funding potential, efforts should be made to create interdisciplinary programs with the departments or professors available to support the objectives and curriculum needs of such education.

All students should have instruction in and knowledge of, quantitative methods, data processing techniques, economic and sociological principles applied to health care, pharmacy practice and marketing systems.

A more enlightened, sophisticated and mobile society is now encountered by the health professions. The population no longer is willing to accept mystique or secretive activities. Health professionals are expected to explain their policies and actions, to justify their monopolies (licenses) and fees. The rapid rise in the number of medical malpractice suits is a proxy indicator of the public's attitudes and needs; it is also a proxy indicator of the levels of satisfaction and quality of care. Literally hundreds of health-area specialties and subspecialties for professionals and paraprofessionals alike have come into existence through informal and formal credentialing. We must learn about the continual developments in health care delivery.

In addition, the Social Pharmacy area has contributed in many more subtle, indirect and long-term ways. It has courageously acted as the social conscience of the profession. Sometimes this has been unpopular and created awkward situations, but fortunately, this has not deterred us from speaking up when voices were needed to help us see the trees through the forest. It is all too easy to lose sight of the patient who is the entire raison d'etre for our profession.

Those drugs we employ are complex substances in reality and in the minds of people. Barker[3] listed the eleven functions he sees of drugs:
These include:

1) Aesthetic functions
2) Aphrodisiac functions
3) Ego-disrupting functions
4) Ideological functions
5) Political functions
6) Psychological functions
7) Religious functions
8) Research functions
9) Social Control functions
10) Therapeutic functions
11) War and other Conflict functions

We must understand the uses of and needs for drugs within society if we are to serve society by any activity beyond mere drug distribution.

While it is easier said than done, that is how it should be done in the opinion of one educator deeply involved in this area.

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## APPENDIX A

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# INSTRUCTIONAL METHODOLOGIES IN CLINICAL PHARMACY EDUCATION

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## INTRODUCTION

Approaching the subject of instructional methodologies in clinical pharmacy education requires, if you will, a certain spirit fostered by the Bicentennial Celebration during the year 1976. Clinical education in pharmacy is presently yet a frontier to be conquered and its conquerors are of the same enthusiasm that tamed the West and spurred the development of space travel. But conquering, in terms of the frontier as well as education, requires one to stand back - to introspectively and peripherally look at what we are trying to do for the present and where the present is taking us for the future. More pointedly, before we examine some specific methodologies for instruction in the frontier of clinical pharmacy, let us examine some philosophical considerations that are prerequisites (in my mind anyway) to effective clinical instruction.

Let us examine the following propositions:

The teaching/learning process in clinical pharmacy education should:

Be a MELDING CONTINUUM which blends the range of instructor-directedness to student-directedness with the range of theoretical principles to effective application in clinical practice.

... Be an ACTIVE PROCESS in which student, instructor and patient uniquely share ideas, decisions and actions

... Continually draw upon past experiences of the learner including the foundational science areas as well as personal growth

... Be ACCOMODATIVE to the variety of learner styles and learning preferences

... Be composed of a VARIETY OF FORMS dictated by the nature, the subject matter, the intended outcomes of the learning experience and the degree of expectations for continued competence.

... Instill a sense of CONFIDENCE and ACCOMPLISHMENT in the learner so the student not only will feel free to use what he has learned but of equal importance, call upon the impressions that were made by recalling favorable learning experiences.

## INSTRUCTIONAL METHODOLOGIES

Through careful examination of the propositions offered above, we should be impressed by the complexity of the instrutional process in clinical education.

We should be equally impressed with the diverse and almost infinite methodologies for instruction that may be utilized to meet the intended goals of clinical instruction. There are several methodologies being experimented with in colleges and schools of pharmacy that specifically encompass the proposition mentioned previously and draw upon tremendous diversity. To review and subsequently analyze the usefulness of these methodologies, again I would propose that four major OUTCOMES or EXPECTATIONS of the teaching/learning process be kept in mind:

1. A Broad Knowledge Base
11. Capability for Problem Detection
111. Capability for Problem Solving
1V. Effectiveness for Interpersonal Relations

These four OUTCOME areas superimposed upon the continuum of instructor/student directness produce a model for instructional design as depicted in Figures 1 and 2. This model illustrates the optimally desired outcome of pharmacy education - that of preparing a practitioner who can be patient - effective in terms of clinical competence and the accompanying levels of confidence that make for effective patient/pharmacist relationships. By more closely examining the model now in terms of its content (Figure 2), we can see the need for a variety of instructional methodologies emerge. To be more specific, let us examine the various levels and quadrants (Figures 3, 4, 5, and 6).

The expected outcome, as shown in Figure 3, of this portion of the instructional process is a KNOWLEDGE base primarily founded in the didactic and experimental components of the curriculum and the "work rounds" of clinical practice. Basic elements of instruction for meeting the KNOWLEDGE OUTCOME have traditionally centered on instructor-directed lectures and laboratories within defined time periods. At the University of Illinois College of Pharmacy, an experiment is progressing in which basic didactic instruction takes place in the form of self-instructional learning packages (133 quarter hours or 37 course curriculum courses). Moreover, competency is demanded and achieved irregardless of time - the student may attain the desired competencies at a rate commensurate with his abilities and motivations. This type of self-directed learning fosters behavior along the lines of the proposition presented earlier. A variety of instructional modes, including computer-aided instruction (CAI), audio and video presentations as well as "paper and pencil" learning units are used as the basis for transmitting an organized mass of knowledge to the student. The continued application of knowledge through computer gaming simulations and the more traditional socratic clinical teaching rounds are effectively uses as mechanisms to assure retention and application of the knowledge base.

Figure 4 constructs the instructional methodological complexities of the desired PROBLEM DETECTION OUTCOME phase of the model. Teaching someone to detect problems in clinical education (or for any other areas of education for that matter) presents a very real problem in instruction - one that is highly dependent upon the flexibility and imaginative prowess of the instructional staff. Clinical simulations utilizing a variety of traditional as well as newer technologies may be effectively employed. Especially useful resources for this area of instruction are interactive computer systems such as PLATO, TICCIT and others. These systems can interact with the student by evaluating responses provided by the learner and subsequently tracking him into a level of the total program that is cognizant of the learner's abilities. Although these systems are initially quite expensive and difficult to design, a number of COUSORTIA users have formed (i.e. health science campus users groups) to spread cost and time investments across multiple groups.

The outcome of PROBLEM SOLVING (Figure 5) abilities to be achieved through the teaching/learning process is equally demanding of innovation and creativity. Didatic and laboratory instruction in the clinical setting can be effectively carried out to develop and foster problem solving abilities in the student. Methodologies that may be approached in fostering PROBLEM SOLVING outcomes might include; but not limited to:

1) Patient problem simulations presented via interactive computers (ie. PLATO)

2) Patient problem simulations presented via branched programmed learning utilizing teaching machines (ie. AutoTutor)

3) Patient problem simulations presented via video based upon real or imaginary patients

4) Problem profiling based upon the concepts of the Problem Oriented Chart (POC) in which simulated problems are "dissected" and plans for their resolve outlined

5) Problem forecasting based upon known principles of therapeutics that would predict patient outcomes given alternative therapies or disjunctive therapies

It should be emphasized here that problem detection and problem solving abilities are highly related to the personal characteristics of student and instructor alike. It can not be assumed that students can detect and solve problems as quickly and throughly as clinical faculty. Therefore, the chosen methodology should be able to account for individual learning styles and learning preferences.

An outcome of the clinical education process that has been less studied relative to the outcomes of knowledge, problem detection and problem solving is that of INTERPERSONAL RELATIONS (Figure 6). Here we consider the foundations of human interaction and hence, social interaction in the health care environment. The instructional process in this complex milieus should focus on making the learner comfortable, in terms of confidence in his abilities and interactive capabilities, when relating to peers, patients and other health care personnel. In its most important sense, the development of interpersonal relations as an outcome for clinical pharmacy education represents the end-point of a socialization process that inherently makes the student cognizant of himself as a clinical practitioner.

Active engagement of the student in the communicative processes that represent development of interpersonal relations is therefore a must. Early learning in this area may be greatly facilitated using one or more of several techniques frequently used in the development of communication and interviewing skills such as;

1) Simulated interviewing of patients using closed circuit television

2) Role playing and role-reversals in which patient encounters are analyzed

3) Interprofessional patient study sessions in which the psychological and social needs of the patients are assessed parallel to his medical needs

4) Patient interaction analysis in which the students' interaction with patients are monitored with closed circuit television and later analyzed by faculty and students alike

5) Patient education techniques which call upon the student to educate the patient about his disease and the drug therapies used to treat the diagnosed problems

## CONCLUSIONS AND IMPLICATIONS

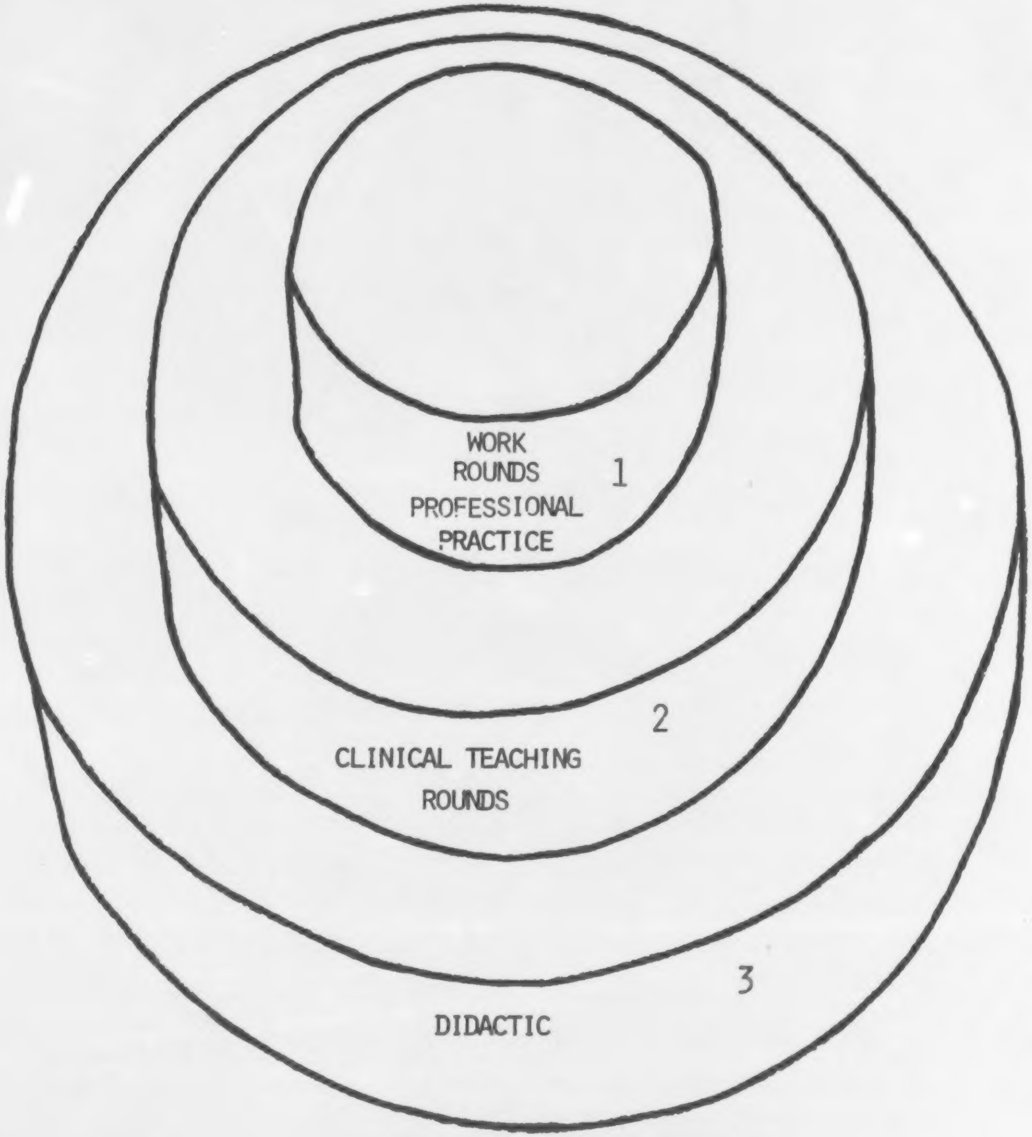
this paper has attempted to review the multiple outcomes envisioned as emanating from the clinical pharmacy educational program. When these intended outcomes were superimposed upon several philosophical propositions about the learner and the intents of clinical pharmacy education, the potential for a variety of innovative instructional techniques was suggested. It was shown that effective instructional processes in clinical education should focus on moving along a continuum that moves from instructor centeredness to student centeredness so that active participation of the learner in the instructional process is assured. Moreover, the development of a sense of confidence and accomplishment should be a central component of the clinical instructional process.

What is implied in analyzing clinical education from the instructional methodology point of view is the fact that clinical pharmacy instruction is the most crucial approximation of future practice realities that the student will ever be immersed in. In no other areas of course work at the undergraduate level does the student become actively involved in the instructional process. Furthermore, in no other area of his coursework is he forced to "step out" and integrate everything he already knows with elements of "real life" problems presented to him by the patients encountered in the clinical setting.

Each of these "peculiarities" of clinical instruction should form the foundations on which clinical instructional processes are designed. There are no set guidelines or rules for effective clinical instruction *per se* but there are a number of instructional methodologies that can be employed to blend what the learner brings to the learning environment with what the learning environment brings to the learner. It is the effective and student-sensitive faculty person that can knowingly capitalize on that "blend" for the design of opitmal instruction.

Clinical education by its very nature calls on the instructional process to be flexible and accomodative to student needs. Thus, it must consistently be centered on the question, "what is it that we are trying to accomplish"? As the answer to this question changes, obviously the instructional strategy will most likely change.

FIG. 1


WORK
ROUNDS
PROFESSIONAL
PRACTICE
1
2
CLINICAL TEACHING
ROUNDS
3
DIDACTIC

Pharmacy
Practitioner

Instructor
Student
Participation

Instructor
Directed

1 PATIENT EFFECTIVENESS
CLINICAL COMPETENCE

2 CLINICAL INSTRUCTION
APPLICATION

3 THEORETICAL PREPARATION
ACADEMIC BACKGROUND

FIG. 2

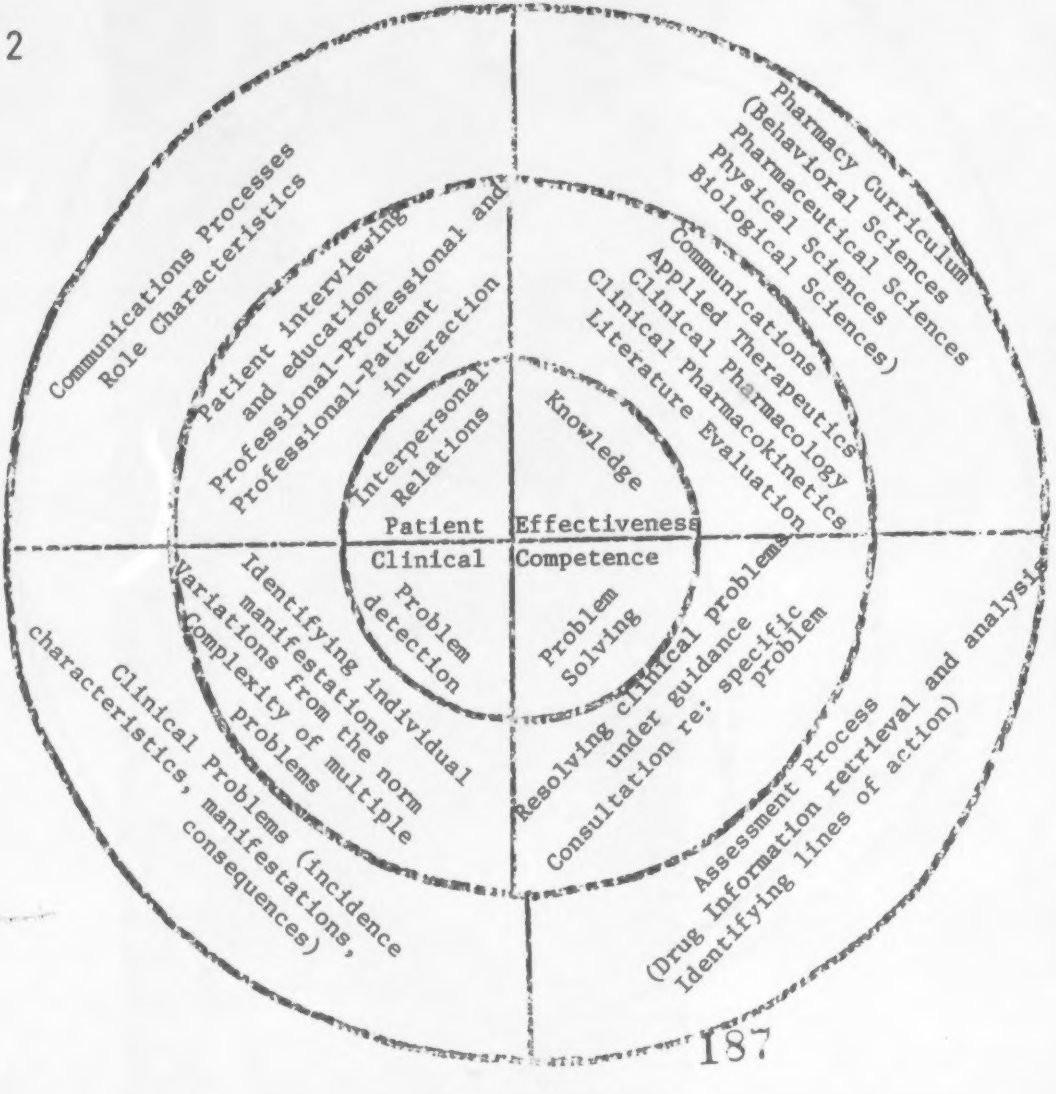
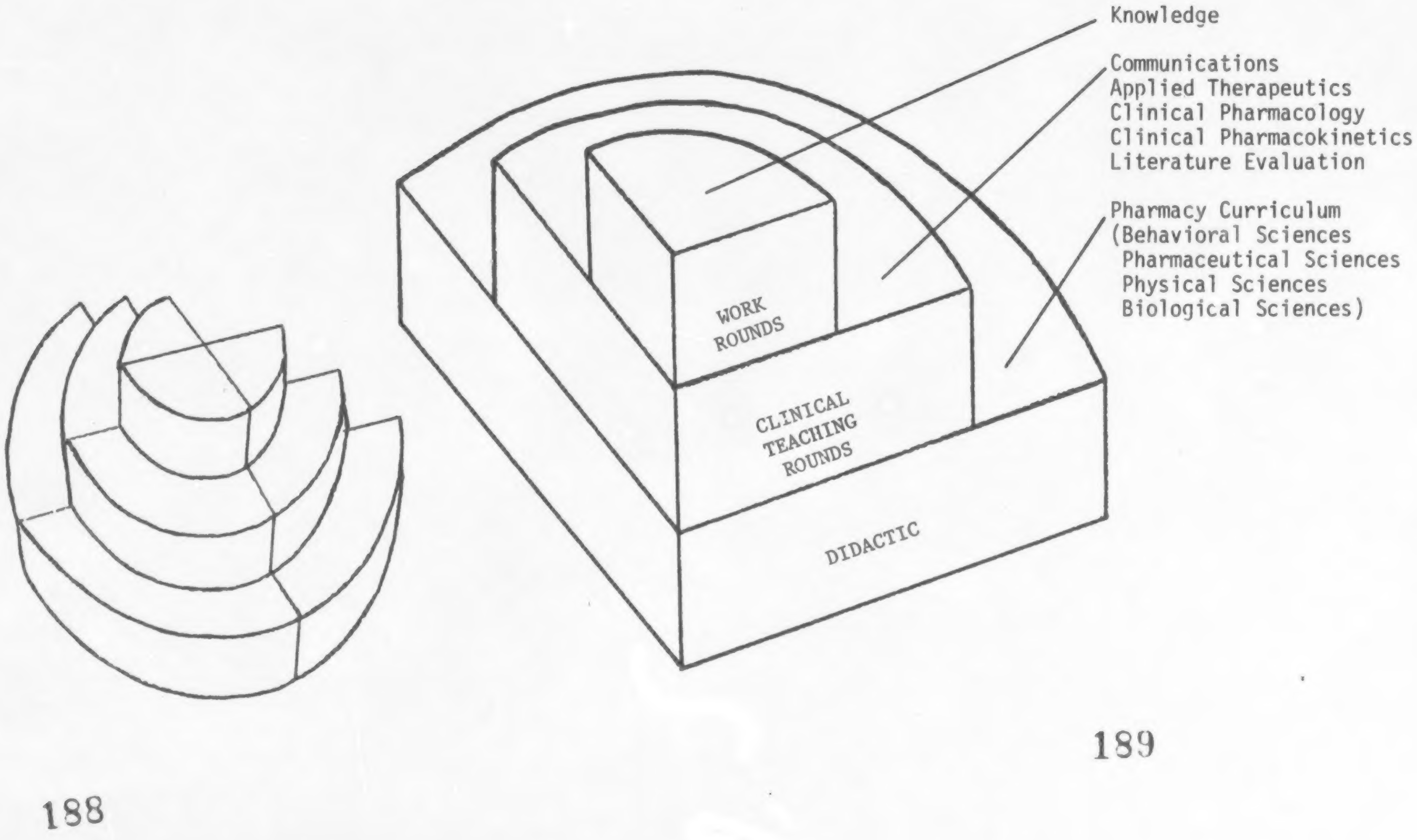

Communications Processes
Role Characteristics
Patient interviewing
and education
Professional-Professional and
Professional-Patient
interaction
Interpersonal
Relations
Pharmacy Curriculum
(Behavioral Sciences
Pharmaceutical Sciences
Physical Sciences
Biological Sciences)
Communications
Applied Therapeutics
Clinical Pharmacology
Clinical Pharmacokinetics
Literature Evaluation
Knowledge
Patient
Effectiveness
Clinical
Competence
Problem
detection
Identifying individual
manifestations
Variations from the norm
Complexity of multiple
problems
Clinical Problems (incidence
characteristics, manifestations,
consequences)
Problem
Solving
Resolving clinical problems
under guidance
Consultation re: specific
problem
Assessment Process
(Drug Information retrieval and analysis
Identifying lines of action)

FIG. 3


Knowledge
Communications
Applied Therapeutics
Clinical Pharmacology
Clinical Pharmacokinetics
Literature Evaluation
Pharmacy Curriculum
(Behavioral Sciences
Pharmaceutical Sciences
Physical Sciences
Biological Sciences)
WORK ROUNDS
CLINICAL TEACHING ROUNDS
DIDACTIC
189
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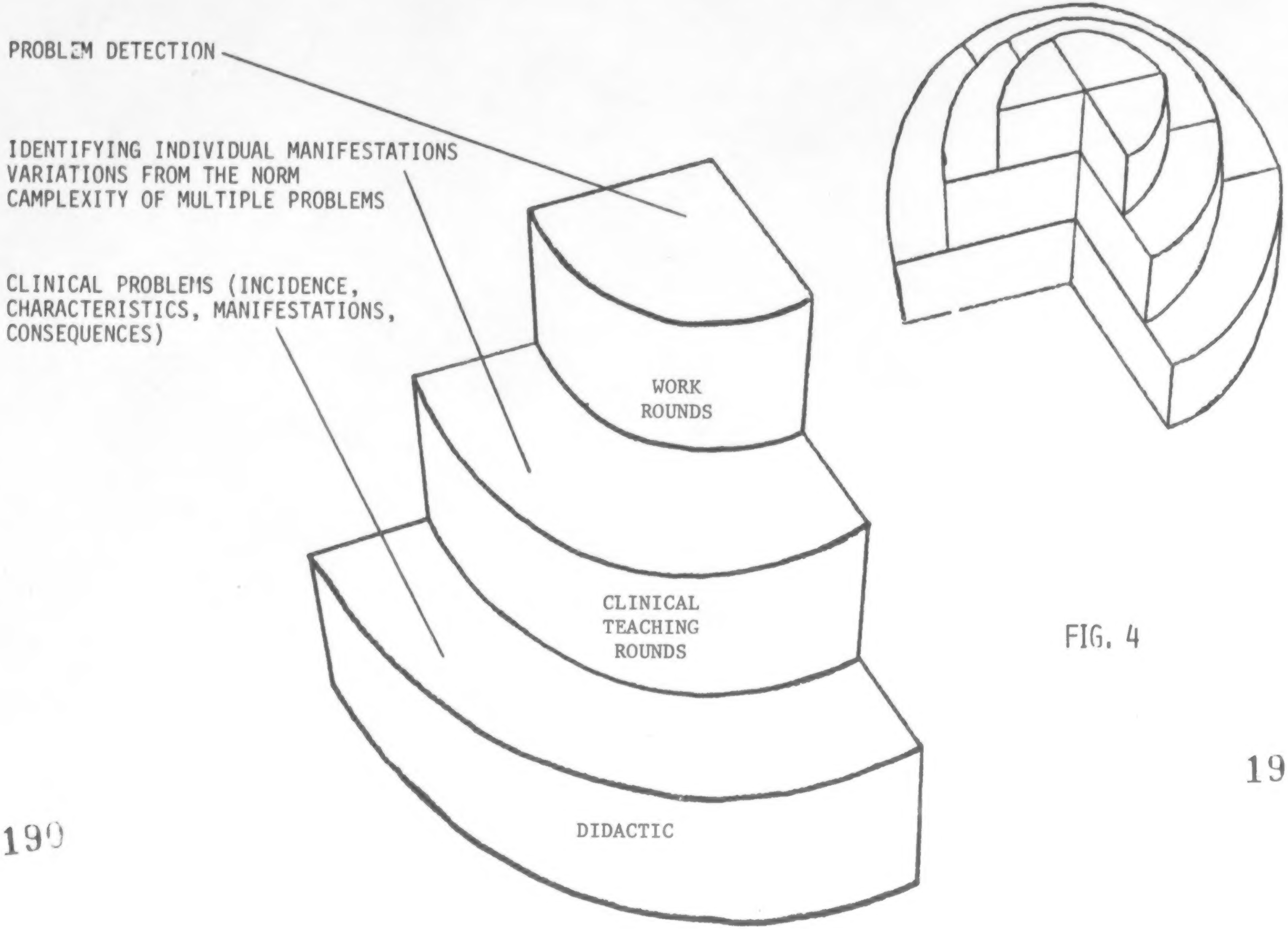
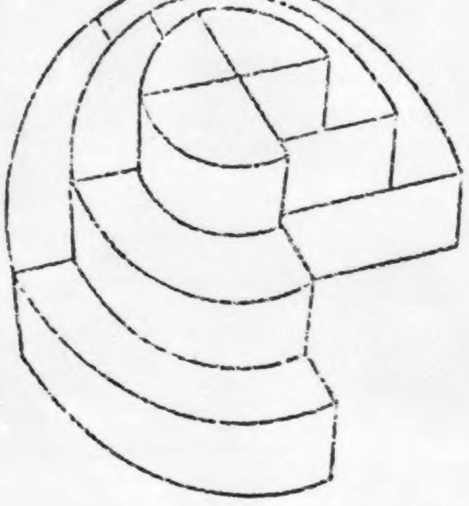

PROBLEM DETECTION
IDENTIFYING INDIVIDUAL MANIFESTATIONS
VARIATIONS FROM THE NORM
CAMPLEXITY OF MULTIPLE PROBLEMS
CLINICAL PROBLEMS (INCIDENCE, CHARACTERISTICS, MANIFESTATIONS, CONSEQUENCES)
WORK ROUNDS
CLINICAL TEACHING ROUNDS
DIDACTIC

FIG. 4



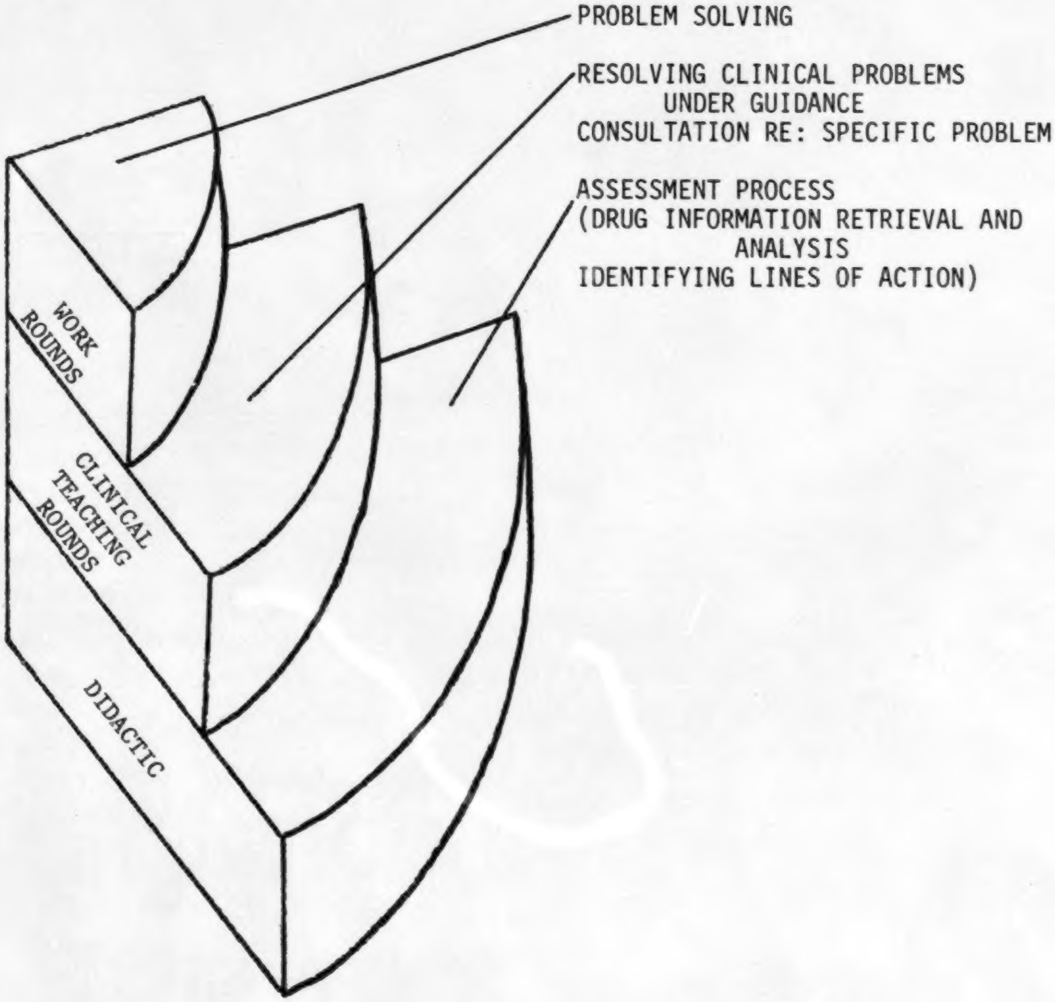
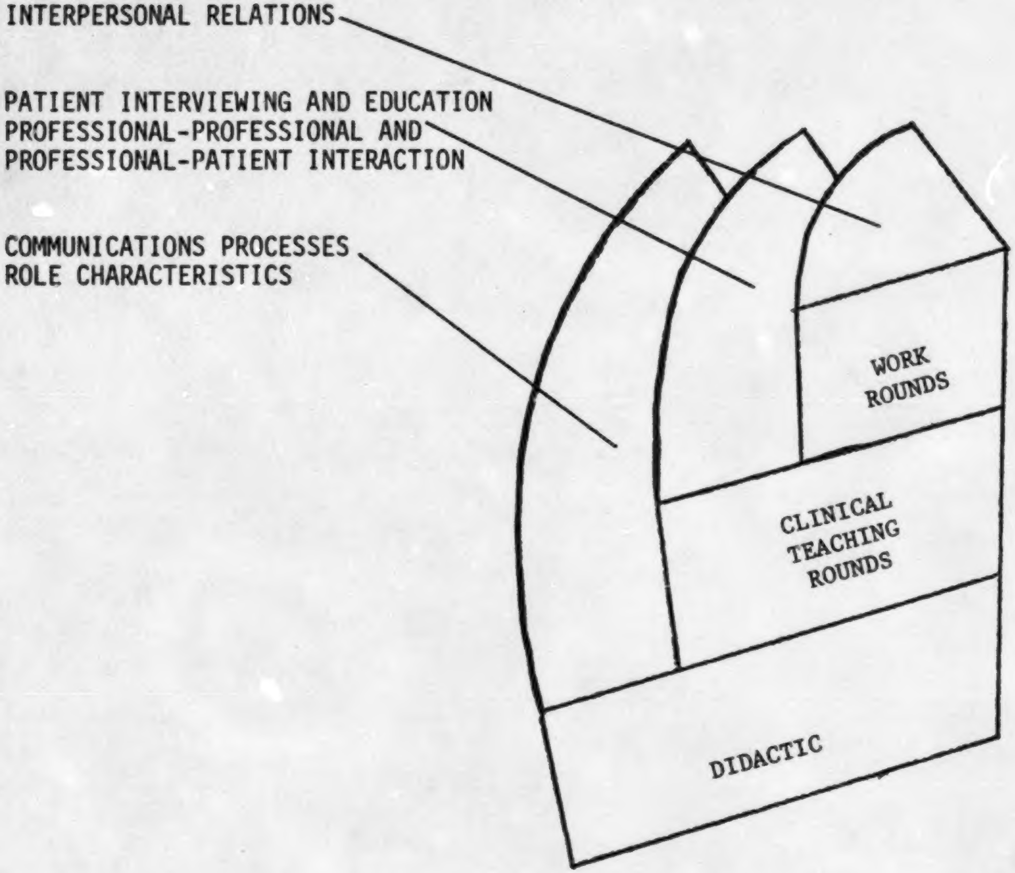

PROBLEM SOLVING
RESOLVING CLINICAL PROBLEMS UNDER GUIDANCE
CONSULTATION RE: SPECIFIC PROBLEM
ASSESSMENT PROCESS
(DRUG INFORMATION RETRIEVAL AND ANALYSIS
IDENTIFYING LINES OF ACTION)
WORK ROUNDS
CLINICAL TEACHING ROUNDS
DIDACTIC

FIG. 5

FIG. 6


INTERPERSONAL RELATIONS
PATIENT INTERVIEWING AND EDUCATION
PROFESSIONAL-PROFESSIONAL AND
PROFESSIONAL-PATIENT INTERACTION
COMMUNICATIONS PROCESSES
ROLE CHARACTERISTICS
WORK ROUNDS
CLINICAL TEACHING ROUNDS
DIDACTIC

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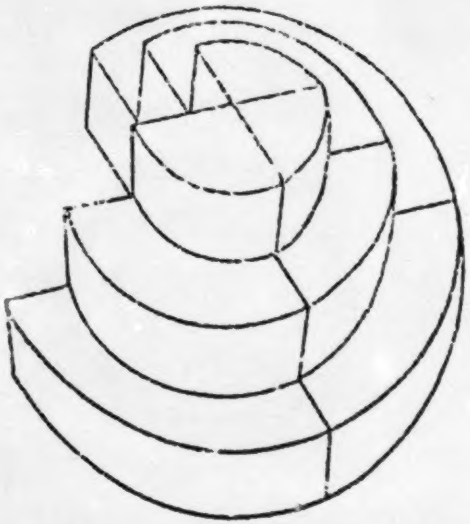

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## CONCLUDING REMARKS

Lawrence C. Weaver, Ph.D., Dean, College of Pharmacy, University of Minnesota.

Over the past three days, you have been exposed to leaders in the development of the clinical pharmacy component of education in North America. I am confident that they are pleased with the opportunity to share their frustrations, failures and, most of all, successes. All this effort was not to get you to duplicate our programs, since your needs are different in many respects from those facing us. Nevertheless, there will be approaches and parts of program that might become useful as you design a new curriculum to produce a pharmacist who can accomplish expanded pharmaceutical services for the health care needs of the people you serve. Such assistance will make our efforts worthwhile.

If you identify need for more assistance in your efforts to develop clinical pharmacy education, you should not hesitate to contact any of the speakers. Perhaps a more exciting involvement might be to identify a Pharmacy school in North America which could support your efforts. We recognize that such an arrangement would benefit both schools. If this interests you, the AACP and/or I would be glad to assist you in bringing about such a cooperative effort.

We recognize that it has taken a special effort for each of you to attend this first International Congress. I am sure that for each of you it represents a worthwhile investment. There does seem to be a need for continued effort to acquaint educators in pharmacy with each others' advances. I would hope that one of you would consider planning the second International Congress on Clinical Pharmacy Education in a few years.

I would encourage each of you to visit other North American pharmacy schools before you return to your homes. Finally, I wish to express the sincere appreciation of the University of Minnesota College of Pharmacy and the AACP to the speakers for an excellent program and to the participants whose enthusiasm has made this Congress so very worthwhile.

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University of Minnesota, July 1976

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Wales
Iran